UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, Plaintiff, -against- CENTERS FOR DISEASE CONTROL AND PREVENTION, AND DEPARTMENT OF HEALTH & HUMAN SERVICES, Defendant.	Civil Action No. 2:23-cv-00102

APPENDIX IN SUPPORT OF PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

NOW COMES, Plaintiff Freedom Coalition of Doctors for Choice and files this Appendix in support of its Plaintiff's Memorandum of Law in Support of its Motion for Summary Judgment.

Exhibit	Description	Page No.
A	Declaration of Chris Wiest, Esq.	0001-0163
B	Declaration of Dr. Richard Bartlett	0164-0169

/s/
John C. Sullivan
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* *pro hac vice* application forthcoming

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

On July __, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all counsel and/or pro se parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

DATED: July __, 2023

/s/
John C. Sullivan
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Attorneys for Plaintiff

Exhibit 1

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DECLARATION OF CHRISTOPHER WIEST, ESQ.

I, Christopher Wiest, declare as follows:

1. I am counsel for Plaintiff, Freedom Coalition of Doctors for Choice.
2. The purpose of this declaration is to support Plaintiff's motion for summary judgment.
3. I make this Declaration based upon my personal knowledge and information available to me in my professional capacity.
4. CDC contracted with a third party, General Dynamics Information Technology, Inc. ("**GDIT**")—for an initial amount of $6,491,148.18—to "convert[] the free text responses in v-safe to standardized MedDRA [The Medical Dictionary for Regulatory Activities] terms." *See* Exhibit A. This contract between CDC and GDIT reveals that all the responsive records at issue in this matter already exist in CSV (comma-separate values) format; this is how the records are sent to GDIT from CDC. What this means is that although there is a large volume of responsive records (each capped at 250 characters in length), these records are in a CSV file that already exists and that is easily searchable. Further, CDC has

already agreed to pay to have individuals manually review each and every free-text field for the purpose of converting them into standardized codes. *See* Exhibit A.

5. On January 3, 2023, Plaintiff, through Counsel, submitted a FOIA request to CDC seeking:

> All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded). Exhibit B.

6. Pursuant to 5 U.S.C. § 552(a)(6)I(i)(I), the request also sought expedited processing based on a demonstrated "compelling need." *Id*. Plaintiff also sought a waiver of fees pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" And it explained why the disclosure of the requested information would contribute to the public's understanding. *Id.*

7. On January 4, 2023, CDC acknowledged the request, assigned it number 23-00462-FOIA, and denied Plaintiff's request for expedited processing and for a fee waiver. *See* Exhibit C.

8. On January 12, 2023, CDC issued its final determination regarding the request which stated in relevant part:

> Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:
> - There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).
> - The agency lacks the resources to manually review the data collected from these registrants.

Exhibit D.

9. On January 13, 2023, Plaintiff submitted an appeal challenging CDC's improper withholding of the responsive records to HHS. *See* Exhibit E.

10. On January 17, 2023, CDC and HHS acknowledged the January 13, 2023 appeal and stated, in relevant part:

> Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Exhibit F.

11. On March 31, 2023, Plaintiff submitted an appeal challenging CDC's improper denial of the fee waiver, *see* Exhibit G, which HHS acknowledged receipt of on April 3, 2023, *see* Exhibit H.
12. CDC and HHS subsequently failed to make a final determination on these appeals within twenty business days as required by FOIA.
13. CDC and HHS also failed to make a final determination on these appeals within the ten additional business days permitted by FOIA.
14. CDC has not discussed with Plaintiff how it could effectively limit the scope of the request.
15. Earlier this year, I attended a meet and confer with Mr. Jody Lowenstein, Attorney at U.S. Department of Justice and counsel for Defendants, and he stated that absent a court order Defendants will not produce the records requested by Plaintiff through FOIA.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury the foregoing to be true and correct, to the best of my knowledge, information and belief.

Executed this 3 day of July, 2023.

CHRISTOPHER WIEST

Exhibit A

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 42

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER	2. CONTRACT NO. *(If any)*
09/26/2022	GS35F080CA

3. ORDER NO.	4. REQUISITION/REFERENCE NO.
75D30122F15339	00HCBCD9-2022-65385

5. ISSUING OFFICE *(Address correspondence to)*
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

7. TO:

a. NAME OF CONTRACTOR
GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
UEI: SMNWM6HN79X5

b. COMPANY NAME

c. STREET ADDRESS
3150 FAIRVIEW PARK DR STE 100

d. CITY	e. STATE	f. ZIP CODE
FALLS CHURCH	VA	22042-

6. SHIP TO:

a. NAME OF CONSIGNEE
CDC/CCID/NCPDCID/DHQP

b. STREET ADDRESS
1600 CLIFTON ROAD NE
BUILDING 16

c. CITY	d. STATE	e. ZIP CODE
ATLANTA	GA	30329-4018

f. SHIP VIA

8. TYPE OF ORDER

[X] a. PURCHASE REFERENCE
YOUR: quote dated 8/25/22
Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.

[X] b. DELIVERY
Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA
9390GLY 2512 2022 75-2124-0943 C5B8111101

10. REQUISITIONING OFFICE
HCBCD9

11. BUSINESS CLASSIFICATION *(Check appropriate box(es))*
[ ] a. SMALL [X] b. OTHER THAN SMALL [ ] c. DISADVANTAGED [ ] d. WOMEN-OWNED

12. F.O.B. POINT	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE *(Date)*	16. DISCOUNT TERMS
Destination		09/27/2023	Net 30 Days

13. PLACE OF

a. INSPECTION	b. ACCEPTANCE

17. SCHEDULE ***(See reverse for Rejections)***

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED
	Vendor Point of contact (b)(6) *Contracts Administrator Sr. Advisor* *Official Authorized Representative* (b)(6) CDC COR: Roberts, Traci Sinetta, Public Health Analyst (CDC/DDID/NCEZID/DHQP) EM.: xct6@cdc.gov /Tel. 404.498.0669 CDC Contract Specialist: Kathryn Green, (CDC/OCOO/OFR/OAS) ezj7@cdc.gov "See Continuation Page"					

18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.	Estimated, Not -to-exceed (b)(4)	17(h) TOT. Cont.

21. MAIL INVOICE TO:

SEE BILLING INSTRUCTIONS ON REVERSE

a. NAME
Centers for Disease Control and Prevention (FMO)

b. STREET ADDRESS *(or P.O. Box)*
PO Box 15580 404-718-8100

c. CITY	d. STATE	e. ZIP CODE	Estimated, Not -to-exceed $6,491,148.18	17(i) GRAND TOTAL
Atlanta	GA	303330080		

22. UNITED STATES OF AMERICA *(Signature)* ▶ Kristopher Lemaster -S
Digitally signed by Kristopher Lemaster -S
Date: 2022.09.07 08:47:09 -04'00'

23. NAME *(Typed)*
Kristopher Lemaster
TITLE: CONTRACTING/ORDERING OFFICER

NSN 7540-01-152-8083
PREVIOUS EDITION NOT USABLE

OPTIONAL FORM 347 (REV. 6/95)
Prescribed by GSA/FAR 48 CFR 53.213(e)

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

Base Period – Year 1 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	V-Safe MedDRA Coding (T&M) As an independent entity, and not as an agent of the US Government, the vendor shall provide all labor and materials necessary to support CDC programmatic efforts to code symptomatic information provided in the free text responses of V-safe health check-in surveys using the Medical Dictionary for Regulatory Activities (MedDRA) terms. Work shall be performed IAW/tasks 1-10 of Section 5 of the Statement of Work (SOW) in Section C that follows. Period of Performance (PoP): 9/26/2022 – 9/25/2023 Services are determined to be severable.	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B811110 (b)(4)			
0002	Other Direct Costs (ODCs) T&M Anticipated materials include, but are not limited to, tokens, secure fax lines, phone and software licenses, delivery fees, reference guides, books and training materials. POP: 9/26/2022 - 9/25/2023	1 Job		
	Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B81111((b)(4)			
Estimated Total - Base Period				

***Not-to-exceed**

Option 1 - Year 1 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0003	Surge Support/V-Safe MedDRA Coding (T&M) Responses to unanticipated demands for increased capacity of services within existing capabilities covered under Sect 5 of the SOW, Task 11, that may require a "surge" in service efforts and/or resources. PoP: Up to 12 months from date option is exercised. Option may be exercised within 9/26/2022 - 9/25/2023. Services are determined to be severable.	1 Job	(b)(4)	

***Not-to-exceed**

Option 2 - Year 2 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
1001	V-Safe MedDRA Coding (T&M) As an independent entity, and not as an agent of the US Government, the vendor shall provide all labor and materials necessary to support CDC programmatic efforts to code symptomatic information provided in the free text responses of V-safe health check-in surveys using the Medical Dictionary for Regulatory Activities (MedDRA) terms. Work shall be performed IAW/tasks 1-10 of Section 5 of the Statement of Work (SOW) in Section C that follows. PoP: 9/26/2023 - 9/25/2024 Services are determined to be severable.	1 Job	(b)(4)	
1002	Other Direct Costs (ODCs) T&M Anticipated materials include, but are not limited to, tokens, secure fax lines, phone and software licenses, delivery fees, reference guides, books and training materials. PoP: 9/26/2023 - 9/25/2024	1 Job		
1003	Surge Support/V-Safe MedDRA Coding (T&M) Responses to unanticipated demands for increased capacity of services within existing capabilities covered under Sect 5 of the SOW, Task 11, that may require a "surge" in service efforts and/or resources. PoP: Up to 12 months from date option is exercised. Option may be exercised within 9/26/2022 - 9/25/2023. Services are determined to be severable.	1 Job		
Estimated Total Year 2				

***Not-to-exceed**

Option 3 - Year 3 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
2001	V-Safe MedDRA Coding (T&M) As an independent entity, and not as an agent of the US Government, the vendor shall provide all labor and materials necessary to support CDC programmatic efforts to code symptomatic information provided in the free text responses of V-safe health check-in surveys using the Medical	1 Job	(b)(4)	

	Dictionary for Regulatory Activities (MedDRA) terms. Work shall be performed IAW/tasks 1-10 of Section 5 of the Statement of Work (SOW) in Section C that follows. PoP: 09/26/2024 - 09/25/2025 Services are determined to be severable.			
2002	Other Direct Costs (ODCs) T&M Anticipated materials include, but are not limited to, tokens, secure fax lines, phone and software licenses, delivery fees, reference guides, books and training materials. PoP: 9/26/2024 - 9/25/2025	1 Job	(b)(4)	
2003	Surge Support/V-Safe MedDRA Coding (T&M) Responses to unanticipated demands for increased capacity of services within existing capabilities covered under Sect 5 of the SOW, Task 11, that may require a "surge" in service efforts and/or resources. PoP: Up to 12 months from date option is exercised. Option may be exercised within 9/26/2024 - 9/25/2025. Services are determined to be severable.	1 Job		
Estimated Total Year 3				

***Not-to-exceed**

Notes:

1. This is a Time and Materials (T&M) type contract under GSA MAS 54151HEAL *Health Information Technology Services*. All Applicable and Required provisions/clauses set forth in FAR 52.301 automatically flow down to all 54151HEAL task orders, based on their specific contract type (e.g. cost, fixed price, etc.), statement of work, competition requirements, commercial or not commercial, and dollar value as of the date the task order solicitation is issued. Representation and Certification Provisions from the 54151HEAL master contracts automatically flow down to all task orders.. FAR Part 12 applies.

2. Supply of anticipated ODC's such as tokens, secure fax lines, phone and software licenses, delivery fees, reference guides, books and training materials are considered "Materials". Payment for these items will be made IAW/FAR Clause 52.212-4 Alternate I (ii) Materials, paragraph (D) (1) Other Direct Costs. The vendor shall obtain the approval of the Contracting Officer's Representative to purchase materials needed for the performance of the work. The Government will reimburse the vendor for any material purchased on the basis of actual cost.

3. The Government has identified several Option Periods of performance. Option Periods will be exercised by written unilateral modification to the contract IAW/Option Clauses included in section D of this RFQ.

4. Optional Surge Support Services CLINs are to be exercised, independently, multiple times, within the corresponding period of performance up to the total ceiling price indicated in the price schedule. The

Contracting Officer will provide a preliminary written notification of intent to exercise any optional surge support CLIN within 10 days from the date the option is scheduled to be exercised. The estimated values of the Optional Surge Support Services CLINs will be adjusted based on the date they will be exercised.

5. The total period of performance is 36 months from the effective date of award, base and options included, as follows:

Year 1: 09/26/2022 – 09/25/2023

Year 2: 09/26/2023 – 09/25/2024

Year 3: 09/26/2024 – 09/25/2025

6. Vendor Point of contact: (b)(6)
Contracts Administrator Sr. Advisor
Official Authorized Representative
(b)(6)

7. Government Point of Contact: Roberts, Traci Sinetta, Public Health Analyst (CDC/DDID/NCEZID/DHQP)
EM.: xct6@cdc.gov /Tel. 404.498.0669

8. Prices have been established at a ceiling, which, if the vendor exceeds, it would be at its own risk. Payment will be made on a monthly basis of in accordance with FAR Clause 52.212-4 Alternate I (Nov 2021). (i) Payments (1) i, Hourly rate, which requires the vendor to show clearly the level of effort provided per month, i.e., number of labor hours, number of days and labor categories employee. The following tables identify the vendor's anticipated level of effort (LoE) per period of performance:

Year 1

Task	VTF V-Safe Labor Category	MAS ITHeal Labor Category	Hours					
			Base	OY 1	Total	Base	OY 1	Total
Task 1-10	(b)(4)		(b)(4)					
Task 1-10								
Task 1-10								
Task 1-10								
Task 1-10								
Task 1-10								
Task 1-10								

Task 1-10	(b)(4)	(b)(4)	
Task 1-10			
Task 1-10			
Task 1-10			
Task 11			
Task 11			
Task 11			
Task 11 Total			
Year 1 Total Estimated LoE			(b)(4)

Year 2

Task	VTF V-Safe Labor Category	MAS ITHeal Labor Category	Hours	Discounted Rate	Total
Task 1-10	(b)(4)		(b)(4)		
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10 Total					

Task 11	(b)(4)	(b)(4)
Task 11		
Task 11		
Task 11 Total		
Year 2 Total Estimated LoE		

Year 3

Task	VTF V-Safe Labor Category	MAS ITHeal Labor Category	Hours	Discounted Rate	Total
Task 1-10	(b)(4)		(b)(4)		
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10					
Task 1-10 Total					
Task 11	(b)(4)				
Task 11					
Task 11					
Task 11 Total					
Year 3 Total Estimated LoE					

Section C - Statement of Work

COVID-19 Vaccine Task Force, Vaccine Safety Team – V-safe Data Services

SECTION 1-Background

On December 31, 2019, the emergence of a severe coronavirus infection with marked associated morbidity and mortality, not previously seen in humans was reported in Wuhan, China. Initial outbreak data from China showed a near exponential growth in reported cases. In response to a rapidly increasing number of reported cases outside of China, on March 11, 2020 the World Health Organization declared the novel coronavirus (COVID-19) outbreak a global pandemic. As of January 22, 2021, there are more than 97,855,365 confirmed cases worldwide with 2,099,047 deaths, of which more than 24,694,145 confirmed cases and 411,781 deaths were in the United States (https://coronavirus.jhu.edu/). The etiologic agent (SARS-Cov-2 virus) is closely related to the Severe Acute Respiratory Syndrome (SARS) coronavirus (SARS-Cov-1) and is transmitted primarily by the respiratory route. In the United States, the number of severe hospitalized cases and deaths across many states declined with the introduction of physical control measures including shelter at home, social distancing, and individual use of cloth masks. However, since late 2020 there has been a resurgence in infections and deaths reported, fueled by fast spreading variants of the SARS-CoV-2 virus that have been first seen in the U.K., South Africa, Brazil, and the United States.

On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued the first emergency use authorization for a vaccine for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. The emergency use authorization allowed the Pfizer-BioNTech COVID-19 vaccine to be distributed in the United States. Shortly after, on December 18, 2020, the FDA issued an emergency use authorization for the second COVID-19 vaccine. The emergency use authorization allowed the Moderna COVID-19 vaccine to be distributed in the U.S for use in individuals 18 years of age and older. As of January 2021, large-scale (Phase 3) clinical trials are in progress for three additional COVID-19 vaccines in the United States. According to the CDC, as of January 22, 2021, 19,107,959 total COVID-19 vaccine doses have been administered in the United States.

The initial phase of the U.S. Government's widespread vaccination program includes individuals at high risk of COVID-19 exposure like essential workers, front-line workers, and healthcare workers—all groups which include substantial numbers of women of reproductive age. Furthermore, the FDA's EUA and CDC's Advisory Committee on Immunization Practices (ACIP) have allowed for pregnant persons who fall into these vaccination priority groups to receive COVID-19 vaccines.

As part of safety monitoring efforts for COVID-19 vaccines, the COVID-19 Vaccine Task Force (VTF) Vaccine Safety Team has developed v-safe, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after people receive a COVID-19 vaccine. Through v-safe, COVID-19 vaccine recipients can quickly indicate if they have any side effects after getting the COVID-19 vaccine. V-safe participants are sent electronic health check-in reminders at the following time points: daily on days 0-7 following vaccination, weekly days 14-42, and monthly at 3, 6, and 12 months. If the participant receives a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through the previously outlined health check-ins based on time since the 2nd dose. At each health check-in, participants are presented with a list of symptoms to check and given the option to enter any additional symptoms they may want to report as free text.

As of August 16, 2021, approximately 122,955,377 v-safe surveys have been submitted. Of these, approximately 4%, or 4,918,215.08, have free text responses. In order to analyze these text fields, we require a consistent coding scheme to organize these free text responses into well-defined symptoms/conditions. The Medical Dictionary for Regulatory Activities (MedDRA) is highly specific standardized international dictionary of medical terminology. Converting the free text responses in v-safe to standardized MedDRA terms will allow these data to be effectively analyzed. This activity will improve the analyzability of v-safe data, enhance the value of v-safe safety surveillance data for FDA and CDC, and facilitate the development of an informative public use data set for v-safe.

SECTION 2-Objective
The objective of this contract is to provide CDC with programmatic support to code symptomatic information provided in the free text responses of V-safe health check-in surveys using MedDRA terms.

SECTION 3-Scope of work
Independently and not as an agent of the Government, the Contractor shall provide all personnel and services necessary to perform the following tasks as listed in this SOW. Services in this SOW are to meet the needs of our critical COVID-19 vaccine safety activities. This work will support the U.S. COVID-19 vaccination program's vaccine safety programs conducted by CDC.

SECTION 4-Working hours
The contractor shall provide services during normal working hours, which are defined as Monday through Friday, 9 a.m. to 5 p.m. Since this is an emergency response effort, it is possible that some of the contractor's services will also be required outside of normal working hours, including on weekends. The Contracting Officer Representative (COR) will provide contractor management with instruction and authorization when services outside of normal working hours are require and when the contractor is needed work over 40 hours per week. Requirement for work outside of normal working hours and additional hours may be given on short notice.

SECTION 5-Tasks to be performed
The contractor shall perform the following tasks under the direction of the VTF Vaccine Safety Team:\

Task 1: In accordance with the CDC v-safe protocol and CDC's v-safe Standard Operating Procedures (SOP), the Contractor shall train representatives how to MedDRA code using the most updated version of MedDRA (http://www.meddra.org/) for each of the text fields of the v-safe surveys.

Task 2: The contractor will convert symptomatic information entered by v-safe participants reported at each of the v-safe health check-ins from three text fields ("healthcare visit—other," "systemic reaction—other," and "symptoms—description") into MedDRA lower and preferred term levels. Only incident medical conditions should be included, any historical medical conditions should not be coded. For example, if a text field indicates long-term cancer, this is not considered an incident medical condition. These health check-in surveys that include text fields are: 8 daily surveys (days 0-7 post-vaccination), weekly surveys (weeks 2-6 post-vaccination), and monthly surveys (months 3, 6, and 12 post-vaccination). If a person receives two vaccines, the health check-in schedule will start at Day 0. There are some populations that may receive a third COVID-19 dose and may enroll into v-safe. The health check-in schedule will start at Day 0 at this third dose.

Task 3: Given that there is currently a backlog of surveys, the contractor shall develop and provide a **plan for getting the backlog** caught up within 3 months of initiating the contract. Surveys will be prioritized in the following order: 1) participant required medical attention, 2) participant was unable to work, 3) participant was unable to complete daily activities, 4) all others.

Task 4: The contractor will also **propose a plan** on how to prospectively code text fields from health check in surveys. The contractor shall plan on coding at least 10,000 text fields per week.

Task 5: The contractor shall establish a secure file transfer protocol (SFTP) site with CDC to allow data extracts to be uploaded and downloaded. In the event a SFTP site cannot be established, the contractor shall provide other suitable mechanisms which are CDC approved to ensure secure transfer of data. CDC will upload a weekly incremental data extract in comma-separated values (CSV) format to the contractor's SFTP site. The data extract will include a survey response ID and three text fields: "healthcare visit—other," "systemic reaction—other," and "symptoms—description". Every week the contractor will post **three cumulative CSV files** onto their SFTP site, one file per text fields. Each CSV file will include the survey response ID and the associated MedDRA terms (lower level and preferred term) for the text field; each MedDRA term will have a separate field.

Task 6: The Contractor shall conduct regular data management and quality control checks per CDC on the data coded. Changes made due to **data quality checks** should be logged in Excel and provided weekly. The weekly cumulative data files sent to CDC will include the most current MedDRA coding (lower and preferred term levels) of all text fields.

Task 7: The contractor shall develop and draft a **weekly status report**. The report shall include but not be limited to weekly/cumulative/average numbers of fields that have been coded and entered. The Contractor will utilize this report as a method to document weekly progress as well as challenges and barriers encountered. The components of the weekly report will be finalized and discussed with the CDC.

Task 8: The Contractor shall initiate a kickoff meeting within one week of the contract. The Contractor will participate on a minimum of one weekly conference call with the Government. The Contractor will be responsible for coordinating calls, inviting all participants, providing dial-in details, take meeting minutes for each call and distributing **meeting minutes** to all call participants within a week after the meeting.

Task 9: The Contractor shall provide a **Final Report** recapping all tasks herein, including any barriers/limitations that need to be considered based on the data collection process.

Task 10: The Contractor shall provide a clinical lead on staff to answer questions and monitor coding.

Task 11 – Surge Support

Additional support: Refer to Task 3 of this Section. Based on the enrollment, attrition, and new populations who may enroll into v-safe and pursuant to federal guidance and COVID-19 vaccine approval, the requirement of MedDRA coding 10,000 text fields may need to increase or decrease. The vendor shall notify the Government of average number of text fields to code per week and if there is a backlog of reports that need to be coded.

SECTION 6- Deliverable schedule

Item	*Deliverable*	*Format*	*Quantity/Recipient*	*Delivery Date*	*Reference*
1	Plan for getting backlog caught up	Word Document (by e-mail)	1 to COR, TM (E)	Within two weeks of contract	Task 3
2	Plan for prospective surveys	Word Document (by e-mail)	1 to COR, TM (E)	Within two weeks of contract	Task 4
3	Weekly clean cumulative dataset in a CSV format	Uploaded via SFTP (by e-mail)	1 to COR, TM (E)	Ongoing	Task 5
4	Change log of data quality checks	Word Document (by e-mail)	1 to COR, TM (E)	Ongoing	Task 6
5	Weekly status report	Word Document (by e-mail)	1 to COR, TM (E)	Weekly	Task 7
6	Meeting minutes	Word Document (by e-mail)	1 to all meeting attendees, COR, TM (E)	Within 7 days of scheduled call with CDC	Task 8
7	Final report recapping contract activities	Word Document (by e-mail)	1 to COR, TM (E)	Month 12 of contract	Tasks 1-11

SECTION 7 - Place of Performance:

It is anticipated that the work will be performed at the vendor's site.

SECTION 8 - Period of Performance: The period of performance shall be 36 months as follows:

Base Period – Year 1:	September 26, 2022 - September 25, 2023
Option 1- Year 2:	September 26, 2023 - September 25, 2024
Option 2- Year 3:	September 26, 2024 - September 25, 2025

SPECIAL CONSIDERATIONS

IT SECURITY

The below information complies with CDC Security and Privacy compliance requirements for E-Government Act of 2002 (FISMA 2002) and Federal Information Security Modernization Act of 2014 (FISMA 2014) Security Compliance

- If the contractor will host or create an information system on behalf of the CDC, provide IT services to the CDC, or provide IT products to the CDC, then the contractor shall comply with the applicable IT security references below (Standards 1 - 4).

Standard-1: Procurements Requiring Information Security and/or Physical Access Security

A. Baseline Security Requirements

1) **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
   a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
   b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) employee will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

2) **Safeguarding Information and Information Systems.** In accordance with the Federal Information Processing Standards Publication (FIPS)199, *Standards for Security Categorization of Federal Information and Information Systems*, the Contractor (and/or any subcontractor) shall:
   a. Protect government information and information systems in order to ensure:
      - **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
      - **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
      - **Availability**, which means ensuring timely and reliable access to and use of information.
   b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less**, bring the situation to the attention of the other party.
   c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov.
   d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

3) **Information Security Categorization**. In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, *Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories*, Appendix C, and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	[ ] Low [x] Moderate [ ] High
Integrity:	[ ] Low [x] Moderate [ ] High
Availability:	[ ] Low [x] Moderate [ ] High
Overall Risk Level:	[ ] Low [x] Moderate [ ] High

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [x] Yes PII

4) **Personally Identifiable Information (PII).** Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [ ] Low [x] Moderate [ ] High

5) **Controlled Unclassified Information (CUI).** CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 32 CFR,* part 2002*)* when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "h*andling"* refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:
   a. marked appropriately;
   b. disclosed to authorized personnel on a Need-To-Know basis;
   c. protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations* if handled by internal Contractor system; and
   d. returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, *Guidelines for Media Sanitization*.

6) **Protection of Sensitive Information**. For security purposes, information is *or* may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, *Protection of Sensitive Agency Information* by securing it with a FIPS 140-2 validated solution.

7) **Confidentiality and Nondisclosure of Information**. Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and *[CDC]* policies. Unauthorized disclosure of information will be subject to the HHS/*[CDC]* sanction policies and/or governed by the following laws and regulations:

   a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
   b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
   c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

8) **Internet Protocol Version 6 (IPv6).** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, *Transition Planning for Internet Protocol Version 6 (IPv6)*. .

9) **Government Websites.** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

10) **Contract Documentation**. The Contractor shall use provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

11) **Standard for Encryption.** The Contractor (and/or any subcontractor) shall:
   a. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.
   b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
   c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and CDC-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
   d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.
   e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to CDC Cybersecurity Program Office (CSPO).

12) **Contractor Non-Disclosure Agreement (NDA)**. Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the CDC non-disclosure agreement, as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

13) **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)** – The Contractor shall assist the CDC Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
   a. The Contractor shall assist the CDC SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the CDC SOP that a review is required based on a major change to the system (e.g., new uses of information collected, changes to the way information is shared or disclosed and for what purpose, or when new types of PII are collected that could introduce new or increased privacy risks), whichever comes first.

B. Training

1) **Mandatory Training for All Contractor Staff.** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/CDC Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete *CDC Security Awareness Training (SAT), Privacy,* and Records Management training at least ***annually***, during the life of this contract. All provided training shall be compliant with HHS training policies.

2) **Role-based Training.** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training (RBT) ***within 60 days*** of assuming their new responsibilities. Thereafter, they shall complete RBT at least ***annually*** in accordance with HHS policy and the *HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum*.
All HHS employees and contractors with SSR who ***have not*** completed the required training within the mandated timeframes shall have their user accounts disabled until they have met their RBT requirement.
Training Records. The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within ***30 days*** after contract award and ***annually*** thereafter or upon request.

C. Rules of Behavior

1) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior.*
2) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least ***annually*** thereafter, which may be done as part of annual *CDC Security Awareness Training*. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

D. Incident Response

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose.

OMB Memorandum M-17-12, "Preparing for and Responding to a Breach of Personally Identifiable Information" (03 January 2017) states:

> **Definition of an Incident:**
>
> *An occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.*
>
> **Definition** of a **Breach:**
>
> *The loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose.*

It further adds:

> A breach is not limited to an occurrence where a person other than an authorized user potentially accesses PII by means of a network intrusion, a targeted attack that exploits website vulnerabilities, or an attack executed through an email message or attachment. A breach may also include the loss or theft of physical documents that include PII and portable electronic storage media that store PII, the inadvertent disclosure

of PII on a public website, or an oral disclosure of PII to a person who is not authorized to receive that information. It may also include an authorized user accessing PII for an other than authorized purpose.

The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines a breach as "a suspected or confirmed incident involving PII".

Contracts with entities that collect, maintain, use, or operate Federal information or information systems on behalf of CDC shall include the following requirements:

1) The contractor shall cooperate with and exchange information with CDC officials, as deemed necessary by the CDC Breach Response Team, to report and manage a suspected or confirmed breach.
2) All contractors and subcontractors shall properly encrypt PII in accordance with OMB Circular A-130 and other applicable policies, including CDC-specific policies, and comply with HHS-specific policies for protecting PII. To this end, all contractors and subcontractors shall protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
3) All contractors and subcontractors shall participate in regular training on how to identify and report a breach.
4) All contractors and subcontractors shall report a suspected or confirmed breach in any medium as soon as possible and no later than 1 hour of discovery, consistent with applicable CDC IT acquisitions guidance, HHS/CDC and incident management policy, and United States Computer Emergency Readiness Team (US-CERT) notification guidelines. To this end, the Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC) or CDC Computer Incident Response Team (CSIRT) within 24 hours via email at csirt@cdc.gov or telephone at 866-655-2245, whether the response is positive or negative.
5) All contractors and subcontractors shall be able to determine what Federal information was or could have been accessed and by whom, construct a timeline of user activity, determine methods and techniques used to access Federal information, and identify the initial attack vector.
6) All contractors and subcontractors shall allow for an inspection, investigation, forensic analysis, and any other action necessary to ensure compliance with HHS/CDC Policy and the HHS/CDC Breach Response Plan and to assist with responding to a breach.
7) Cloud service providers shall use guidance provided in the FedRAMP Incident Communications Procedures when deciding when to report directly to US-CERT first or notify CDC first.
8) Identify roles and responsibilities, in accordance with HHS/CDC Breach Response Policy and the HHS/CDC Breach Response Plan. To this end, the Contractor shall NOT notify affected individuals unless and until so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, all notifications must be pre-approved by the appropriate CDC officials, consistent with HHS/CDC Breach Response Plan, and the Contractor shall then send CDC-approved notifications to affected individuals; and,
9) Acknowledge that CDC will not interpret report of a breach, by itself, as conclusive evidence that the contractor or its subcontractor failed to provide adequate safeguards for PII.

E. Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR).

The requiring activity representative, in conjunction with Personnel Security, shall use the OPM Position Sensitivity Designation automated tool (https://www.opm.gov/investigations/) to determine the sensitivity designation for background investigations. After making those determinations, include all applicable position sensitivity designations.

F. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2.*

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO by the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted immediately upon change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

If the employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level.

G. Contract Initiation and Expiration

1) **General Security Requirements.** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Guide (2012).

HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html CDC EPC Requirements: https://www2a.CDC.gov/CDCup/library/other/eplc.htm

2) **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, *Security Considerations in the System Development Life Cycle*, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
3) **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, *Guidelines for Media Sanitization*.
4) **Notification.** The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO before an employee stops working under this contract.
5) **Contractor Responsibilities Upon Physical Completion of the Contract**. The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or *CDC* policies.
6) The Contractor (and/or any subcontractor) shall perform and document the actions identified in the CDC Out-Processing Checklist (http://intranet.cdc.gov/od/hcrmo/pdfs/hr/Out_Processing_Checklist.pdf) when an employee terminates work under this contract. All documentation shall be made available to the CO and/or COR upon request.

H. Records Management and Retention

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration

(NARA) records retention policies and schedules and HHS policies and shall not dispose of any records unless authorized by HHS.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS policies.

Standard-2: Requirements for Procurements Involving Privacy

Appropriate security controls and Rules of Behavior should be incorporated to protect the confidentiality of information, proprietary, sensitive, and Personally Identifiable Information (PII) the Contractor may come in contact with during the performance of this contract.

Standard-3: Procurements Involving Government Information Processed on GOCO or COCO Systems

A. Security Requirements for GOCO and COCO Resources

1) **Federal Policies.** The Contractor (and/or any subcontractor) shall comply with applicable federal directives that include, but are not limited to, the *HHS Information Security and Privacy Policy (IS2P)*, the *CDC Protection of Information Resources* policy; *Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101)*; National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, *Security and Privacy Controls for Federal Information Systems and* Organizations; Office of Management and Budget (OMB) Circular A-130*, Managing Information as a Strategic Resource*; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.

2) **Security Assessment and Authorization (SA&A)**. A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO prior to any use of the system in a production capacity, i.e., its intended users able to collect, store, process or transmit data to fulfill the system's function. The Contractor shall conduct the SA&A requirements in accordance with *HHS IS2P/ CDC Protection of Information Resources*; the *CDC IT Security Program Implementation Standards;* the *CDC Security Assessment and Authorization (SA&A) Standard Operating Procedure;* and NIST SP 800-37, *Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach* (latest revision).

CDC acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

a. SA&A Package Deliverables - The Contractor (and/or any subcontractor) shall provide an SA&A package to the C/I/O Information System Security Officer (ISSO) in accordance with the timeline, process and formats proscribed for a Full system authorization in the CDC Security Assessment and Authorization Standard Operating Procedure (CDC SA&A SOP). The following SA&A deliverables are required to complete the SA&A package:

- **Baseline System Information (BSI)** – The Contractor will document a system overview, in accordance with the timeline, process and formats described in the *CDC SA&A SOP*. The BSI will include information concerning: system identification and ownership; system data, information types, impact levels and system categorization; system functional description / general purpose; system authorization boundary and environment; system user descriptions; and system interconnections and dependencies. The Contractor shall update the BSI at least ***annually*** thereafter.
- **Privacy Threshold Analysis / Privacy Impact Analysis** – The Contractor (and/or any subcontractor) shall provide a PTA/PIA (as appropriate), in accordance with the timeline, process and formats described in the *CDC SA&A SOP*, if applicable. Also see the sections of this contract concerning "Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)" and "Requirements for Procurements Involving Privacy Act Records."

  NOTE: If social security numbers (SSN) are expected to be handled by the system, the program and Contractor must include an *SSN Elimination or Usage Approval Request* along with the

PTA/PIA. That request will be processed in accordance with the *CSPO Standard for Limiting the Use of Social Security Numbers in CDC Information Systems*.

- **System Security Plan (SSP)** – The SSP must be provided in a digital format supporting copy or export of all content into the HHS/CDC automated SA&A tool. The SSP shall comply with the NIST SP 800-18, *Guide for Developing Security Plans for Federal Information Systems*, the Federal Information Processing Standard (FIPS) 200, *Recommended Security Controls for Federal Information Systems*, and NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline requirements, and other applicable NIST guidance as well as HHS and CDC policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or quote that resulted in the award of this contract. The SSP shall provide an overview of the system environment (including an inventory of all devices and software contained within the system boundary) and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least ***annually*** thereafter.
- **Risk Assessment Report (RAR)** The initial security assessment shall be conducted by the Contractor in conjunction with the program's Information System Security Officer, consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and CDC policies. The assessor will document and submit the assessment results in the RAR, in accordance with the process and formats described in the *CDC SA&A SOP*. The Contractor shall address all *"High"* deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M) for CDC CSPO approval in accordance with the *CDC SA&A SOP*. Thereafter, the Contractor, in coordination with *CDC* shall conduct an assessment of the security controls and update the RAR within 365 days**.**
  POA&M –The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and CDC policies. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the Security Assessment Report (SAR), shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, CDC may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.
- **Contingency Plan and Contingency Plan Test** –The Contingency Plan must be developed in accordance with NIST SP 800-34, *Contingency Planning Guide for Federal Information Systems*, and be consistent with HHS and CDC policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least ***annually***.
- **E-Authentication Assessment** – The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04; NIST SP 800-63, *Digital Identity Guidelines;* the *CSPO Standard for Electronic Authentication (E-Authentication); and* the *CDC SA&A SOP*.
  Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

b. Information Security Continuous Monitoring. Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137,

Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:

- **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party). In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date.
- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least annually. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management** - Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least annually. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least annually.

Critical –	within 15 days
High –	within 30 days
Medium –	within 60 days
Low –	within 350 days

- **Patching and Vulnerability Remediation** - Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeline per CSPO Vulnerability Remediation Framework Standard.
- **Secure Coding** - Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection** - The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

3) **Government Access for Security Assessment**. In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

a. At any tier handling or accessing information, consent to and allow the Government, or an independent

third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross-site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

b. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

c. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.

d. Cooperate with inspections, audits, investigations, and reviews.

4) **End of Life Compliance.** The Contractor (and/or any subcontractor) must use Commercial off the Shelf (COTS) software or other software that is supported by the manufacturer. In addition, the COTS/other software need to be within one major version of the current version; deviation from this requirement will only be allowed via the HHS waiver process (approved by HHS CISO). The contractor shall retire and/or upgrade all software/systems that have reached end-of-life in accordance with HHS *End-of-Life Operating Systems, Software, and Applications Policy*.

5) **Desktops, Laptops, and Other Computing Devices Required for Use by the Contractor**. The Contractor (and/or any subcontractor) shall ensure that all IT equipment (e.g., laptops, desktops, servers, routers, mobile devices, peripheral devices, etc.) used to process information on behalf of HHS are deployed and operated in accordance with approved security configurations and meet the following minimum requirements:

a. Encrypt information categorized as moderate or high impact as required by OMB Memorandum A-130, *Managing Information as Strategic Resource*, in accordance with the HHS *Standard for Encryption of Computing Devices and Information* and FIPS 140-2.

b. Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB) and HHS *Minimum Security Configuration Standards*;

c. Maintain the latest operating system patch release and anti-virus software definitions;

d. Validate the configuration settings after hardware and software installation, operation, maintenance, update, and patching and ensure changes in hardware and software do not alter the approved configuration settings; and

e. Automate configuration settings and configuration management in accordance with HHS security policies, including but not limited to:

- Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and
- Using Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a monthly basis and report the results of these scans to the CO and/or COR, Project Officer, and any other applicable designated POC.

6) **Change Management.** Once a system is authorized, all changes must be approved by CDC in accordance with NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations;*

the *HHS IS2P;* and the timeline, process and formats proscribed in the CDC *CSPO Change Management Standard Operating Procedure*.

7) **Retirement / Decommissioning.** When the CDC program and Contractor determine the system is no longer required, it must be decommissioned in accordance NIST SP 800-88, *Guidelines for Media Sanitization*; the *HHS IS2P;* and the timeline, process and formats proscribed in the CDC *CSPO System Retirement Standard Operating Procedure*.

Standard-4: Contracts Involving Cloud Services

I. HHS FedRAMP Privacy and Security Requirements

The Contractor (and/or any subcontractor) shall be responsible for the following privacy and security requirements:

1) **FedRAMP Compliant ATO**. Comply with FedRAMP Security Assessment and Authorization (SA&A) requirements and ensure the information system/service under this contract has a valid FedRAMP compliant (approved) authority to operate (ATO) in accordance with Federal Information Processing Standard (FIPS) Publication 199 defined security categorization. If a FedRAMP compliant ATO has not been granted, the Contractor shall submit a plan to obtain a FedRAMP compliant ATO.
   a. Implement applicable FedRAMP baseline controls commensurate with the agency-defined security categorization and the applicable FedRAMP security control baseline (www.FedRAMP.gov). The *HHS Information Security and Privacy Policy (IS2P)* and *HHS Cloud Computing and Federal Risk and Authorization Management Program (FedRAMP) Guidance* further define the baseline policies as well as roles and responsibilities. The Contractor shall also implement a set of additional controls identified by the agency when applicable.
   b. A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.
2) **Data Jurisdiction.** The contractor shall store all information within the security authorization boundary, data at rest or data backup, within the continental United States (CONUS) if so required.
3) **Service Level Agreements.** *Add when applicable* The Contractor shall understand the terms of the service agreements that define the legal relationships between cloud customers and cloud providers and work with CDC to develop and maintain an SLA.
4) **Interconnection Agreements/Memorandum of Agreements.** *Add when applicable* The Contractor shall establish and maintain Interconnection Agreements and or Memorandum of Agreements/Understanding in accordance with HHS/CDC policies.

J. Protection of Information in a Cloud Environment

1) If contractor (and/or any subcontractor) personnel must remove any information from the primary work area, they shall protect it to the same extent they would the proprietary data and/or company trade secrets and in accordance with HHS/CDC policies.
2) HHS will retain unrestricted rights to federal data handled under this contract. Specifically, HHS retains ownership of any user created/loaded data and applications collected, maintained, used, or operated on behalf of HHS and hosted on contractor's infrastructure, as well as maintains the right to request full copies of these at any time. If requested, data must be available to HHS within ***one (1) business day*** from request date or within the timeframe specified otherwise. In addition, the data shall be provided at no additional cost to HHS.
3) The Contractor (and/or any subcontractor) shall ensure that the facilities that house the network infrastructure are physically and logically secure in accordance with FedRAMP requirements and HHS policies.
4) The contractor shall support a system of records in accordance with NARA-approved records schedule(s) and protection requirements for federal agencies to manage their electronic records in accordance with 36 CFR § 1236.20 & 1236.22 (ref. a), including but not limited to the following:
   a. Maintenance of links between records and metadata, and
   b. Categorization of records to manage retention and disposal, either through transfer of permanent records to NARA or deletion of temporary records in accordance with NARA-approved retention schedules.

5) The disposition of all HHS data shall be at the written direction of HHS/CDC. This may include documents returned to HHS control; destroyed; or held as specified until otherwise directed. Items returned to the Government shall be hand carried or sent by certified mail to the COR.
6) If the system involves the design, development, or operation of a system of records on individuals, the Contractor shall comply with the contract language herein related to *"*Requirements for Procurements Involving Privacy Act Records*"*.

3. Security Assessment and Authorization (SA&A) Process

1) The Contractor (and/or any subcontractor) shall comply with HHS and FedRAMP requirements as mandated by federal laws, regulations, and HHS policies, including making available any documentation, physical access, and logical access needed to support the SA&A requirement. The level of effort for the SA&A is based on the system's FIPS 199 security categorization and HHS/CDC security policies and in accordance with the contract language herein related to *"*Procurements Involving Government Information Processed on GOCO or COCO Systems*"*.
   a. In addition to the FedRAMP compliant ATO, the contractor shall complete and maintain an agency SA&A package to obtain agency ATO prior to system deployment/service implementation in accordance with the contract language herein related to "Procurements Involving Government Information Processed on GOCO or COCO Systems". The agency ATO must be approved by the CDC Authorizing Official (AO) prior to implementation of system and/or service being acquired.
   b. CSP systems must leverage a FedRAMP accredited third-party assessment organization (3PAO).
   c. For all acquired cloud services, the SA&A package must contain documentation in accordance with the contract language herein related to "Procurements Involving Government Information Processed on GOCO or COCO Systems". Following the initial ATO, the Contractor must review and maintain the ATO in accordance with HHS/CDC policies.
2) HHS reserves the right to perform penetration testing (pen testing) on all systems operated on behalf of agency. If HHS exercises this right, the Contractor (and/or any subcontractor) shall allow HHS employees (and/or designated third parties) to conduct Security Assessment activities to include control reviews in accordance with HHS requirements. Review activities include, but are not limited to, scanning operating systems, web applications, wireless scanning; network device scanning to include routers, switches, and firewall, and IDS/IPS; databases and other applicable systems, including general support structure, that support the processing, transportation, storage, or security of Government information for vulnerabilities.
3) The Contractor must identify any gaps between required FedRAMP Security Control Baseline/Continuous Monitoring controls and the contractor's implementation status as documented in the Security Assessment Report and related Continuous Monitoring artifacts. In addition, all gaps shall be documented and tracked by the contractor for mitigation in a Plan of Action and Milestones (POA&M) document. Depending on the severity of the risks, HHS may require remediation at the contractor's expense, before HHS issues an ATO.
4) The Contractor (and/or any subcontractor) shall mitigate security risks for which they are responsible, including those identified during SA&A and continuous monitoring activities. All vulnerabilities and other risk findings shall be remediated by the prescribed timelines from discovery: (1) critical vulnerabilities no later than ***thirty (30) days*** and (2) high, medium and low vulnerabilities no later ***than sixty (60) days***. In the event a vulnerability or other risk finding cannot be mitigated within the prescribed timelines above, they shall be added to the designated POA&M and mitigated within the newly designated timelines For all system-level weaknesses, the following are specified mitigation timelines from weakness creation date in the POA&M:
   a. **15 days** for critical weaknesses;
   b. **30 days** for high weaknesses;
   c. **60 days** for medium weaknesses; and
   d. **365 days** for low weakness.
   e. HHS will determine the risk rating of vulnerabilities using FedRAMP baselines.
5) **Revocation of a Cloud Service**. HHS/[CDC/OCIO] have the right to take action in response to the CSP's lack of compliance and/or increased level of risk. In the event the CSP fails to meet HHS and FedRAMP security and privacy requirements and/or there is an incident involving sensitive information, HHS and/or */*CDC*]* may suspend or revoke an existing agency ATO (either in part or in whole) and/or cease operations. If an ATO is suspended or revoked in accordance with this provision, the CO and/or COR may direct the CSP to take additional security measures to secure sensitive information. These measures may include restricting access to sensitive information on the Contractor information system under this contract.

Restricting access may include disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls.

K. Reporting and Continuous Monitoring

1) Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.
2) At a minimum, the Contractor must provide the following artifacts/deliverables on a ***monthly*** basis:
   a. Vendor/Contractor that owns infrastructure where the system resides:
      i. Perform periodic Authenticated Vulnerability Scans and Application Scans (if applicable) according to CSPO ISCM guidance
      ii. Perform weekly scans (at a minimum) and provide results to C/I/O/ISSO and CSPO ISCM for systems with a FIPS 199 impact level of High, HVA, or if the system contains PII, and ensure scan results are submitted in either CSV or PDF format
      iii. Remediate vulnerabilities in accordance with CSPO Vulnerability Remediation Framework Policy
      iv. Advise the C/I/O/ISSO for any instance when critical/high vulnerabilities cannot be remediated as in accordance with the CSPO Vulnerability Framework Standard
      v. Submit monthly Authenticated Vulnerability scans and Application scans (if applicable) to CDC (business owner) and C/I/O/ISSO
   b. Business Stewards (such as System Owner):
      i. Confirm Vendor/Contractor is performing Authenticated Vulnerability Scans and Application Scans (if applicable) according to CSPO ISCM guidance
      ii. Review monthly Authenticated Vulnerability Scans and Application Scans (if applicable); Develop POA&Ms as needed
      iii. Submit monthly Authenticated Vulnerability Scans and Application Scans (if applicable) to CSPO ISCM
      iv. Submit written waiver requests to the CISO when systems cannot comply with the provisions of this standard
      v. Track remediation/mitigation of security gaps to closure
   c. Operating system, database, Web application, and network vulnerability scan results;
   d. Updated POA&Ms;
   e. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the System Owner or AO; and
   f. Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/CDC's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

L. Configuration Baseline

1) The contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS-identified configuration baseline. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved HHS/CDC configuration baseline.
2) The contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

M. Incident Reporting

1) The Contractor (and/or any subcontractor) shall provide an Incident and Breach Response Plan (IRP) in accordance with HHS CDC, OMB, and US-CERT requirements and obtain approval from the CDC. In addition, the Contractor must follow the incident response and US-CERT reporting guidance contained in the FedRAMP Incident Communications.

2) The Contractor (and/or any subcontractor) must implement a program of inspection to safeguard against threats and hazards to the security, confidentiality, integrity, and availability of federal data, afford HHS access to its facilities, installations, technical capabilities, operations, documentation, records, and databases within ***72 hours*** of notification. The program of inspection shall include, but is not limited to:
   a. Conduct authenticated and unauthenticated operating system/network/database/Web application vulnerability scans. Automated scans can be performed by HHS/CDC personnel, or agents acting on behalf of HHS/CDC, using agency-operated equipment and/or specified tools. The Contractor may choose to run its own automated scans or audits, provided the scanning tools and configuration settings are compliant with NIST Security Content Automation Protocol (SCAP) standards and have been approved by the agency. The agency may request the Contractor's scanning results and, at the agency discretion, accept those in lieu of agency performed vulnerability scans.
   b. In the event an incident involving sensitive information occurs, cooperate on all required activities determined by the agency to ensure an effective incident or breach response and provide all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. In addition, the Contractor must follow the agency reporting procedures and document the steps it takes to contain and eradicate the incident, recover from the incident, and provide a post-incident report that includes at a minimum the following:
      - Company and point of contact name;
      - Contract information;
      - Impact classifications/threat vector;
      - Type of information compromised;
      - A summary of lessons learned; and
      - Explanation of the mitigation steps of exploited vulnerabilities to prevent similar incidents in the future.

N. Media Transport

1) The Contractor and its employees shall be accountable and document all activities associated with the transport of government information, devices, and media transported outside controlled areas and/or facilities. These include information stored on digital and non-digital media (e.g., CD-ROM, tapes, etc.), mobile/portable devices (e.g., USB flash drives, external hard drives, and SD cards)
2) All information, devices and media must be encrypted with HHS-approved encryption mechanisms to protect the confidentiality, integrity, and availability of all government information transported outside of controlled facilities.

O. Boundary Protection: Trusted Internet Connections (TIC)

1) The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities using cloud services is inspected by Trusted Internet Connection (TIC) processes.
2) The contractor shall route all external connections through a TIC.
3) **Non-Repudiation.** The contractor shall provide a system that implements FIPS 140-2 validated encryption that provides for origin authentication, data integrity, and signer non-repudiation.

Section D – Additional Clauses

FAR 52.204-14 Service Contract Reporting Requirements (Oct 2016)

(a) Definition.

"First-tier subcontract" means a subcontract awarded directly by the Contractor for the purpose of acquiring supplies or services (including construction) for performance of a prime contract. It does not include the Contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies that benefit multiple contracts and/or the costs of which are normally applied to a Contractor's general and administrative expenses or indirect costs.

(b) The Contractor shall report, in accordance with paragraphs (c) and (d) of this clause, annually by October 31, for services performed under this contract during the preceding Government fiscal year (October 1-September 30).

(c) The Contractor shall report the following information:

(1) Contract number and, as applicable, order number.

(2) The total dollar amount invoiced for services performed during the previous Government fiscal year under the contract.

(3) The number of Contractor direct labor hours expended on the services performed during the previous Government fiscal year.

(4) Data reported by subcontractors under paragraph (f) of this clause.

(d) The information required in paragraph (c) of this clause shall be submitted via the internet at www.sam.gov. (See SAM User Guide). If the Contractor fails to submit the report in a timely manner, the contracting officer will exercise appropriate contractual remedies. In addition, the Contracting Officer will make the Contractor's failure to comply with the reporting requirements a part of the Contractor's performance information under FAR subpart 42.15.

(e) Agencies will review Contractor reported information for reasonableness and consistency with available contract information. In the event the agency believes that revisions to the Contractor reported information are warranted, the agency will notify the Contractor no later than November 15. By November 30, the Contractor shall revise the report, or document its rationale for the agency.

(1) The Contractor shall require each first-tier subcontractor providing services under this contract, with subcontract(s) each valued at or above the thresholds set forth in 4.1703(a)(2), to provide the following detailed information to the Contractor in sufficient time to submit the report:

(i) Subcontract number (including subcontractor name and unique entity identifier); and

(ii) The number of first-tier subcontractor direct-labor hours expended on the services performed during the previous Government fiscal year.

(2) The Contractor shall advise the subcontractor that the information will be made available to the public as required by section 743 of Division C of the Consolidated Appropriations Act, 2010.

(End of clause)

Option for Increased Quantity. Separately Priced Line Item

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in

the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within fifteen (15) days from the date the option period starts. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of clause)

FAR 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 10 days prior to the end of the period of performance.

(End of clause)

FAR 52.217-9 - Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 10 days prior to the end of the period of performance, provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 15 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36 months.

(End of clause)

FAR 52.224-1 Privacy Act Notification (April 1984)

The Contractor will be required to design, develop, or operate a system of records on individuals, to accomplish an agency function subject to the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 U.S.C.552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

(End of Clause)

FAR 52.224-2 Privacy Act (April 1984)

(a) The Contractor agrees to –

(1) Comply with the Privacy Act of 1974 (the Act) and the agency rules and regulations issued under the Act in the design, development, or operation of any system of records on individuals to accomplish an agency function when the contract specifically identifies –

(i) The systems of records; and

(ii) The design, development, or operation work that the contractor is to perform;

(2) Include the Privacy Act notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation, when the work statement in the proposed subcontract requires the redesign, development, or operation of a system of records on individuals that is subject to the Act; and

(3) Include this clause, including this subparagraph (3), in all subcontracts awarded under this contract which requires the design, development, or operation of such a system of records.

(b) In the event of violations of the Act, a civil action may be brought against the agency involved when the violation concerns the design, development, or operation of a system of records on individuals to accomplish an agency function, and criminal penalties may be imposed upon the officers or employees of the agency when the violation concerns the operation of a system of records on individuals to accomplish an agency function. For purposes of the Act, when the contract is for the operation of a system of records on individuals to accomplish an agency function, the Contractor is considered to be an employee of the agency.

(c)(1) "Operation of a system of records," as used in this clause, means performance of any of the activities associated with maintaining the system of records, including the collection, use, and dissemination of records.

(2) "Record," as used in this clause, means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and that contains the person's name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint or voiceprint or a photograph.

(3) "System of records on individuals," as used in this clause, means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

(End of Clause)

HHSAR 352.203-70 Anti-Lobbying. (DEC 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations. (Dec. 18, 2015)

(a) In addition to complying with the clause at FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal

Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614. For purposes of this clause, the following definitions apply:

(1) **Complaint** means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) **Contractor employee** means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees~~,~~ who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) **Good faith cooperation** cited in paragraph (a) includes, but is not limited to, making Contractor employees available for:

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;

(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(iii) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations;

(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and

(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

HHSAR 352.231-70 Salary Rate Limitation (Dec 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management Web site for Federal Executive Schedule salary levels.

(End of clause)

HHSAR 352.232-71 Electronic Submission of Payment Requests (February 2, 2022)

(a) Definitions. As used in this clause—
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of Clause)

HHSAR 352.233-71 Litigation and Claims (December 18, 2015)

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment."

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent documents received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by other terms or conditions of this contract, by law or regulation, or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

HHSAR 352.239-74 Electronic and Information Technology Accessibility (December 18, 2015)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers

Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and….

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are: 1194.

205 WCAG 2.0 Level A & AA Success Criteria
302 Functional Performance Criteria
502 Inoperability with Assistive Technology
503 Applications
504 Authoring Tools
602 Support Documentation
603 Support Services

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

CDC0_G008 Contracting Officer's Representative (COR) (Jul 2017)

Performance of the work hereunder shall be subject to the technical directions of the designated COR for this contract.

As used herein, technical directions are directions to the Contractor which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor believes full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer, immediately or as soon as possible, in a letter or e-

mail separate of any required report(s). No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government COR is not authorized to change any of the terms and conditions of this contract. Contract changes shall be made only by the Contracting Officer by properly written modification(s) to the contract. The Government will provide the Contractor with a copy of the COR delegation memorandum upon request.

(End of Clause)

CDCA_H040 GOVERNMENT PROPERTY (JUL 2017)

(a) Government-Furnished Property (GFP). In accordance with the terms of FAR 52.245-1, Government Property, the Government reserves the right to supply the Contractor, as Government-furnished property, any additional supplies, equipment, and materials determined by the Contracting Officer to be necessary and in the best interest of the Government.

(b) Contractor-Acquired Property (CAP). The Contractor must receive written consent from the Contracting Officer prior to purchase of any CAP not expressly identified in the contract, and as defined in FAR 52.245-1.

(c) Accountable and Sensitive Government Property. The Government will provide property labels and other identification for contractor-acquired Government property that is considered Accountable as defined in the HHS Logistics Management Manual (LMM) https://intranet.hhs.gov/abouthhs/manuals/lmm/index.html or considered Sensitive as defined in CDC's Sensitive Items List (http://intranet.cdc.gov/ofr/documents/contracts/Authorized-Prohibited-List.pdf)

(d) The contractor shall be responsible for the control and accountable record keeping of any Government property used in the performance of this contract predominately outside the confines of a Government controlled workspace in accordance with the HHS Contracting Guide found on the OSSAM Government Property and Contractors Property intranet page. (http://intranet.cdc.gov/ossam/property-shipping-receiving/property-management/government-property-contractors/index.html)

(e) The Chief of the Office of Safety, Security and Asset Management (OSSAM), Asset Management Services Office, Centers for Disease Control and Prevention (CDC), is hereby designated as the Property Administrator for this contract. The Contractor shall identify each item of equipment furnished by the Government to the Contractor or acquired by the Contractor using contract funds, with a suitable decal, tag, or other marking, as prescribed by the Property Administrator, and shall follow the guidance set forth in the HHS Contracting Guide.

(End of Clause)

CDC37.0001 Non-Personal Services (June 2020)

a) Personal services shall not be performed under this contract. Although the Government may provide sporadic or occasional instructions within the scope of the contract, the Contractor is responsible for control and supervision of its employees. If the Contractor (including its employees) believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

(b) The contractor shall comply with, and ensure their employees and subcontractors comply with, CDC Policy titled "Contractor Identification and Safeguarding of Non-Public Information". No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. The contractor is limited to performing the services identified in the contract statement of work and shall not interpret any communication with anyone as a permissible

change in contract scope or as authorization to perform work not described in the contract. All contract changes will be incorporated by a modification signed by the Contracting Officer.

(c) The Contractor shall ensure that all of its employees and subcontractor employees working on this contract are informed of the terms and conditions herein. The Contractor agrees that this is a non-personal services contract; and that for all the purposes of the contract, the Contractor is not, nor shall it hold itself out to be an agent or partner of, or joint venture with, the Government. The Contractor shall notify its employees that they shall neither supervise nor accept supervision from Government employees. The substance of the terms herein shall be included in all subcontracts at any tier.

(d) The terms and conditions above do not limit the Government's rights under other terms of the contract, including those related to the Government's right to inspect and accept or reject the services performed under this contract.

(End of Clause)

CDC-42.0002 Evaluation of Contractors Utilizing CPARS (Aug 2021)

In accordance with FAR 42.15, the Centers for Disease Control and Prevention (CDC) will review and evaluate contract performance. FAR 42.1502 and 42.1503 requires agencies to prepare evaluations of contractor performance and submit them to the Contractor Performance Assessment Reporting System (CPARS). The CDC utilizes this web-based system to prepare and report contractor performance evaluations. All information contained in these assessments may be used by the Government, within the limitations of FAR 42.15, for future source selections in accordance with FAR 15.304 where past performance is an evaluation factor.

The CPARS system requires a contractor representative to be assigned so that the contractor has appropriate input into the performance evaluation process. The CPARS contractor representative will be given access to CPARS and will be given the opportunity to concur or not-concur with performance evaluations before the evaluations are complete. The CPARS contractor representative will also have the opportunity to add comments to performance evaluations.

The assessment is not subject to the Disputes clause of the contract, nor is it subject to appeal beyond the review and comment procedures described in the guides on the CPARS website. Refer to: www.cpars.gov for details and additional information related to CPARS, CPARS user access, how contract performance assessments are conducted, and how Contractors participate. Access and training for all persons responsible for the preparation and review of performance assessments is also available at the CPARS website.
The contractor must provide the CDC contracting office with the name, e-mail address, and phone number of their designated CPARS representative who will be responsible for logging into CPARS and reviewing and commenting on performance evaluations. The contractor must maintain a current representative to serve as the contractor representative in CPARS. It is the contractor's responsibility to notify the CDC contracting office, in writing (letter or email), when their CPARS representative information needs to be changed or updated. Failure to maintain current CPARS contractor representative information will result in the loss of an opportunity to review and comment on performance evaluations.

(End of Clause)

CDCA_H042 Records Management Obligations (Jun 2020)

A. *Applicability*
The following applies to all Contractors whose employees create, work with, or otherwise handle Federal records, as defined in Section B, regardless of the medium in which the record exists.

B. *Definitions*
"Federal record" as defined in 44 U.S.C. § 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence

of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.
The term Federal record:

1. includes Centers for Disease Control and Prevention (CDC) records.
2. does not include personal materials.
3. applies to records created, received, or maintained by Contractors pursuant to their CDC contract.
4. may include deliverables and documentation associated with deliverables.

C. *Requirements*

1. Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.
2. In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.
3. In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
4. CDC and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of CDC or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to the Contracting Officer and the Contracting Officer's Representative. The agency must report promptly to NARA in accordance with 36 CFR 1230.
5. The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to CDC control, or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the contract. Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).
6. The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, contracts. The Contractor (and any sub-contractor) is required to abide by Government and CDC guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.
7. The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with CDC policy.
8. The Contractor shall not create or maintain any records containing any non-public CDC information that are not specifically tied to or authorized by the contract.

9. The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.
10. Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take CDC-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.

D. *Flow down of requirements to subcontractors*

1. The Contractor shall incorporate the entire substance of the terms and conditions herein, including this paragraph, in all subcontracts under this contract, and must require written subcontractor acknowledgment of same.
2. Violation by a subcontractor of any provision set forth herein will be attributed to the Contractor.

CDC0_H046 Agency Ombudsman (Feb 2018)

CDC is committed to ensuring fair opportunity for all offerors submitting proposals for competitive task/delivery orders issued against existing Indefinite Delivery Indefinite Quantity contracts in accordance with FAR 16.505. Offerors/Contractors may protest task/delivery order awards of any amount on the grounds that the order increases the scope, period, or maximum value of the contract under which the order was issued. These complaints may be lodged at the agency level or protested with the General Accountability Office (GAO).

Additionally, in accordance with 41 U.S.C. 253(j), protests of task/delivery orders valued in excess of

$10,000,000.00 should be filed directly with the GAO in accordance with FAR 33.104.

In accordance with FAR 16.505(b)(5), CDC has designated an agency Task/Delivery Order Ombudsman who is responsible for reviewing the complaints from contractors on the task/delivery order process. The Ombudsman's responsibility is to review complaints and ensure that all contractors are afforded a fair opportunity to be considered, consistent with procedures in the contract. The Contract Ombudsman is independent of the contracting office. The process for handling complaints under the Ombudsman is as follows:

a) The written complaint must include all the information required for agency protests in FAR 33.103 and must be sent to:

Centers for Disease Control and Prevention
Attn: Sherry Smallwood, Agency
Ombudsman 1600 Clifton Rd, NE

Bldg. 16, Mailstop-C12 Atlanta, GA 30329

Telephone: 404-639-7291

Email: svs9@cdc.gov

Complaints must be submitted to the Agency Ombudsman no later than 10 days after the basis of the protest is known or should have been known, whichever is earlier.

b) The Ombudsman will contact the complainant by phone, to assure full understanding of the issues raised in the protest. This contact will be made within 2 business days of the receipt of the protests by the Ombudsman. Since there is only one individual serving as the agency Task/Delivery Order Ombudsman, there may be protests received when the Ombudsman is in a travel or leave status. In that instance, the Ombudsman will begin action on the complaint immediately upon return to the office.

CDC0_ H049 Non-Disclosure Agreement for Contractor and Contractor Employees. (Jun 2020)

(a) The contractor and contractor employees shall prepare and submit Non-Disclosure Agreements (NDA) to the Contracting Officer prior to access of government information or the commencement of work at CDC.

(b) The NDAs, at Exhibit I and II, are required in service contracts where contractor's employees will have access to non-public and procurement-sensitive information while performing functions in support of the Government. The NDA also requires contractor's employees properly identify themselves as employees of a contractor when communicating or interacting with CDC employees, employees of other governmental entities, and members of the public (when communication or interaction relates to the contractor's work with the CDC). The Federal Acquisition Regulation (FAR) 37.114 (c), states "All contractor personnel attending meetings, answering Government telephones, and working in other situations where their contractor status is not obvious to third parties are required to identify themselves as such to avoid creating an impression in the minds of members of the public or Congress that they are Government officials, unless, in the judgment of the agency, no harm can come from failing to identify themselves. They must also ensure that all documents or reports produced by contractors are suitably marked as contractor products or that contractor participation is appropriately disclosed."

(c) The contractor shall inform contractor employees of the identification requirements by which they must abide and monitor employee compliance with the identification requirements.

(d) During the contract performance period, the contractor is responsible to ensure that all additional or replacement contractors' employees sign an NDA and it is submitted to the Contracting Officer prior to commencement of their work with the CDC.

(e) Contractor employees in designated positions or functions that have not signed the appropriate NDA shall not have access to any non-public, procurement sensitive information or participate in government meetings where sensitive information may be discussed.

(f) The Contractor shall prepare and maintain a current list of employees working under NDAs and submit to the Contracting Officer upon request during the contract period of performance. The list should at a minimum include: contract number, employee's name, position, date of hire and NDA requirement.

Section F – Attachments

EXHIBIT I

Centers for Disease Control and Prevention (CDC)

Contractor Non-Disclosure Agreement

I. Non-public Information

[Name of contractor] understands that in order to fulfill the responsibilities pursuant to [contract name and number] between the Centers for Disease Control and Prevention and [Name of CDC contractor] dated [date], employees of [contractor] will have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

In order to properly safeguard non-public information, [contractor] agrees to ensure that prior to being granted access to government information or the commencement of work for the CDC, whichever is applicable, all contractor employees will sign a Non-Disclosure Agreement (NDA) provided by the CDC prior to beginning work for the CDC. Contractor agrees to submit to the Contracting Officer the original signed copies of NDAs signed by the contractor's employees in accordance with the instructions provided by the Contracting Officer. Failure to provide signed NDAs in accordance with this agreement and instructions provided by the Contracting Officer could delay or prevent the employee from commencing or continuing work at the CDC until such agreement is signed and returned to the Contracting Officer.

Contractor further agrees that it will not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee any non-public information that the employee may obtain in connection with the performance of the employee's responsibilities to the CDC.

II. Procurement-Sensitive Information

Contractor further agrees that it will not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual, other than an authorized Government employee, any procurement-sensitive information gained while in connection with fulfilling the employee's responsibilities at the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Procurement Requests (PR), and Requests for Proposal (RFP); Responses to RFPs, including proposals, questions from potential offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personnel involved in the solicitation; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

Contractor understands and agrees that employee access to any procurement-sensitive information may create a conflict of interest which will preclude contractor from becoming a competitor for any acquisition(s) resulting from this information. Therefore, if an employee participates in any discussions relating to procurement-sensitive information, assists in developing any procurement-sensitive information, or otherwise obtains any procurement-sensitive information while performing duties at the CDC, contractor understands and agrees that contractor may be excluded from competing for any acquisition(s) resulting from this information.

III. Identification of Non-Government Employees

Contractor understands that its employees are not agents of the Government. Therefore, unless otherwise directed in writing by the CDC, contractor agrees to assist and monitor employee compliance with the following identification procedures:

A. At the beginning of interactions with CDC employees, employees of other governmental entities, and members of the public (when such communication or interaction relates to the contractor's work with the CDC), contractors' employees will identify themselves as an employee of a contractor.

B. Contractors' employees will include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages, in connection with contractual duties to the CDC:

Employee's name

Name of contractor

Center or office affiliation

Centers for Disease Control and Prevention

C. At the beginning of telephone conversations or conference calls, contractors' employees will identify themselves as an employee of a contractor.

D. Contractors' employees should not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises. The only other exception is when a CDC management official has granted permission to use the CDC logo.

E. Contractors' employees will program CDC voice mail message to identify themselves as an employee of a contractor.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. Contractor acknowledges that contractor has read and fully understands this agreement.

Name of contractor: _____

Signature of Authorized Representative of Contractor:_____

Date:_____

Copies retained by: Contracting Officer and contractor

EXHIBIT II

Centers for Disease Control and Prevention (CDC)

Contractors' Employee Non-Disclosure Agreement

I. Non-Public Information

I understand that in order to fulfill my responsibilities as an employee of [Name of CDC contractor], I will have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

I, [Name of Employee], agree to use non-public information only in performance of my responsibilities to the CDC. I agree further that I will not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any non-public information that I may obtain in connection with the performance of my responsibilities to the CDC.

II. Procurement-Sensitive Information

I further agree that unless I have prior written permission from the CDC, I will not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any procurement-sensitive information gained in connection with the performance of my responsibilities to the CDC. I specifically agree not to disclose any non-public, procurement-sensitive information to employees of my company or any other organization unless so authorized in writing by the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Procurement Requests (PR), and Requests for Proposal (RFP); Responses to RFPs, including proposals, questions from potential offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personnel involved in the acquisition; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

I understand and agree that my access to any procurement-sensitive information may create a conflict of interest which will preclude me, my current employer, or a future employer from becoming a competitor for any resulting government acquisition derived from this information. Therefore, if I participate in any discussions relating to procurement-sensitive information, assist in developing any procurement-sensitive information, or otherwise obtain any procurement-sensitive information while performing my duties at the CDC, I understand and agree that I, my current employer, and any future employer(s) may be excluded from competing for any resulting acquisitions.

III. Special Non-Disclosure Agreement for Contractors with Access to CDC Grants Management and Procurement-Related Information Technology Systems

In addition to complying with the non-disclosure requirements and safeguards stated above, I understand that my authorization to use CDC's grants management and procurement systems is strictly limited to the access and functions necessary for the performance of my responsibilities to the CDC and which have been approved in advance by the CDC. I understand that I am not authorized to enter procurement requests for any requirements pertaining to contracts or subcontracts held by me or my employer.

IV. Identification as a Non-Government Employee

I understand that as an employee of a government contractor, I represent an independent organization and I am not an agent of the Government. Therefore, I agree that unless I have prior written authorization from the CDC, I will, at the beginning of interactions with CDC employees, employees of other governmental entities, members of the

public (when such communication or interaction relates to the contractor's work with the CDC), identify myself as an employee of a contractor. I further agree to use the following identification procedures in connection with my work at the CDC:

A. I will include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages:

Employee's name

Name of contractor

Center or office affiliation

Centers for Disease Control and Prevention

B. I will identify myself as an employee of a contractor at the beginning of telephone conversations or conference calls;

C. I will not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises; the only other exception is when a CDC management official has granted permission to use the CDC logo.

D. I will program my CDC voice mail message to identify myself as a contractors' employee.

E. I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. I acknowledge that I have read and fully understand this agreement.

Name of contractor: _____

Name of Employee:_____

Signature of Employee:_____

Date:_____

Copies retained by: Contracting Officer, contractor, and Contractor Employee

Attachment 2

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

(b)(4)

(b)(4)

(b)(4)

Exhibit B

Submit New Request

23-00462-FOIA

Requester Details

o modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
Attorney
Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd
Ste. 104
Crestview Hills, KY 41017
Phone 5132571895
chris@cwiestlaw.com

Requester Default Category: All Others

General Information

ction Office	HQ CDC/ATSDR FOIA Office
ction Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
equest Type	FOIA
equester Category	Non-Commercial Scientific
elivery Mode	E-mail

hipping Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

equest Information

escription	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
ate Range for Record earch:From	10/01/2020
ate Range for Record earch:To	12/31/2022
escription Document	CDC v-safe free text request.pdf

ee Information

illing Amount	$25
ee Waiver Requested	Yes ,CDC v-safe free text request.pdf
ee Waiver Request Reason	See attached.
illing to Pay All Fees	No

illing Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills

tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

ther Information

lame	
ompany	
hone	
ax	
mail Address	
treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

xpedite Information

xpedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

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[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Exhibit C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 4, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated January 3, 2023. Your request assigned number is 23-00462-FOIA, and it has been placed in our complex processing queue (copy enclosed).

Extension of Time
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

☐ We reasonably expect to receive and review voluminous records in response to your request.
☐ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Irma S. Diaz at 770-488-6310 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing
You requested that we expedite processing your request. Your request is denied because:
☐ You have failed to show that there is an imminent threat to the life or physical safety of an individual.
☐ You have not demonstrated that you are a person primarily engaged in disseminating information.

Fees and Fee Waivers

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☐ You have failed to demonstrate that you disseminate information to the public.

☐ You have failed to provide enough information to warrant a waiver of fees.

Fee Category

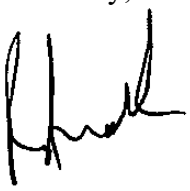
Because you are considered an "Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Appeal Rights

You have the right to appeal the agency's expedited processing and fee waiver response to your request. You may file your appeal with the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 5, 2023

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6310 or via email at jyo0@cdc.gov.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

23-00462-FOIA

Exhibit D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 12, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd. Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 3, 2023. Your request assigned number is 23-00462-FOIA, seeking:

> *"All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).* Date range: 10/01/2020-12/31/2022."

Please click on the following link to download a copy of the public v-safe data released by CDC. The data contains the registrant codes for all participants: *https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d*

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).

- The agency lacks the resources to manually review the data collected from these registrants.

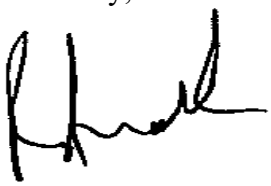
Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

Please click on the following link or copy into a web browser to download a copy of your records (download access is open for 90 days).
https://centersfordiseasecontrol.sharefile.com/d-s43a2254979c94ab6b5c52584509a351f

Appeal Rights

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 13, 2023.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#23-00462-FOIA

Exhibit E

Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

January 13, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request* #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter "Organization"). On January 3, 2023, I submitted on behalf of the Organization a request for records (hereafter "FOIA Request") from the files of the Centers for Disease Control and Prevention (hereafter "CDC") pursuant to the Freedom of Information Act (hereafter "FOIA"). On January 12, 2023, CDC responded to the FOIA Request (hereafter "Final Response"). The Organization writes now to appeal the Final Response.

Background:

On January 3, 2023, the Organization submitted a request to CDC for the following documents:

> *All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*

(Attachment 1.)

On January 12, 2023, CDC issued a Final Response letter which stated in relevant part:

> *Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:*
>
> - *There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).*
>
> - *The agency lacks the resources to manually review the data collected from these registrants.*

> *Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.*

(Attachment 2.)

Argument:

CDC's withholding of the requested free text fields (hereafter "requested records") violates FOIA in two ways. First, CDC has failed to provide any exemption to justify withholding the requested records and a proper final 'determination.' Secondly, even if it has determined that portions of the requested records are not reasonably segregable, and they contain information relevant to protected privacy interests under Exemption 6, CDC has failed to demonstrate whether such privacy interests outweigh the public's interest in disclosure.

1. **CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records.**

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide the Organization with an adequate 'determination' as required under FOIA. When the sufficiency of "the release of information under the FOIA" is challenged, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). "[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C.§ 552(a)(6)(A)(i) ("notify the person making such request of such determination *and reasons therefor*."). "The statutory requirement that the agency provide 'the reasons' for its 'determination' strongly suggests that the reasons are particularized to the 'determination' — most obviously, the specific exemptions that may apply to certain withheld records." *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep't of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency "satisfied its obligation to 'determine and communicate . . . the reasons for withholding any documents" because they "provided reasons by listing and defining the exemptions that the agency applied to the records" withheld.) Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency's obligations under FOIA. *Khine*, 943 F.3d at 967-968.

In this instance, CDC's Final Response did not provide the information necessary to justify its reasoning for withholding records. CDC's Final Response declares "the agency is withholding the v-safe free-text-fields data" but never details the applicable FOIA Exemption that justify its withholding. (*See* Attachment 2). CDC claims all "7.8 million free-text field entries collected from registered users . . . contain personal identifiable information (PII)." *Id*. CDC further claims

that it "lacks the resources to manually review the data collected from these registrants." First, if CDC does not have the resources to manually review the free text fields, how does it know all 7.8 million free text entries contain PII. It does not adequately prove this assertion. Second, CDC has not provided any information on whether most – if not all – the PII can be removed through more automated mechanisms, as opposed to only "manual[] review." For example, Social Security numbers, birthdates, phone numbers, registrant numbers, city names, etc. can likely be redacted through automated mechanism, or at least this information could be flagged for relatively easy manual redactions. Furthermore, if the free text fields are represented in a standardized template, and the PII is routinely detailed in certain boxes or locations in the template, the agency can automate a redaction overlay, that redacts these PII locations on every record. Therefore, CDC has not provided sufficient reasoning to withhold the requested records. For all the reasons described above, CDC has failed to justify withholding the requested records and provide the Organization with a sufficient final 'determination.' *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d 188-89.

2. **CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public's interest under Exemption 6.**

Even if CDC could demonstrate that the unreasonably segregable portions of the requested records contain protected privacy interests, CDC has failed to demonstrate those interests outweigh the public's interests in the requested records. "An agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi AG Media LLC v. U.S. Dep't of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a de minimis, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must "weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy." *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep't of State v. Washington Post Co*., 456 U.S. 595, 598 (1982).

In this instance, CDC's Final Response makes no indication whether the release of the information it has proven cannot be reasonably segregated would cause a "clearly unwarranted invasion of privacy." *Lepelletier*, 164 F.3d 46. FOIA does not flatly prohibit the release of personal information that could cause an invasion of privacy. It only protects the release of personal information that would cause a clearly unwarranted invasion of privacy. Thus, the determination on whether an invasion of privacy is clearly warranted or not depends on the

public's interest and benefit in obtaining the released material. *Id*. In this case, the requested information the Organization seeks has insurmountable importance to the public, and yet CDC's Final Response provides no indication whether the public's interest in the requested records was even considered.

In consideration of this appeal, as CDC goes back to balance the privacy interests in non-disclosure versus the public's interest in disclosure, Organization provides the following information to emphasize the insurmountable public interest in the requested records:

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which CDC currently possesses but is refusing to disclose, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

Failure to disclose this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. This would compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.[4] That is, for example, the core mission of React-19, a non-profit comprised of many individuals, and medical professionals, seriously injured from COVID-19 vaccines.

The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harms – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated. The information derived from the free text fields can help provide information to alleviate some of these issues.

The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign in order to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] The refusal to disclose the requested records would deny families the information they need to provide their informed consent to the external pressures and

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id*.

messaging resulting from the current administration's actions.

Lastly, if the requested information is disclosed, the Organization will, and has the capacity to make the information immediately available to the public. The Organization is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

Appellate Request:

For all the reasons detailed above, the Freedom Coalition of Doctors for Choice appeals CDC's Final Response and requests the agency make a determination with respect to this appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.
Regards,

/s Christopher Wiest
Christopher Wiest

Exhibit F

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00067-A-PHS

January 17, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on January 17, 2023. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

Exhibit G

Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

March 31, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs U.S. Department of Health and Human Services Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: Fee Waiver Appeal of FOIA Request #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter "Freedom Coalition"). On January 3, 2023, on behalf of Freedom Coalition, I submitted a request for records (hereafter "FOIA Request") from the files of the Centers for Disease Control and Prevention (hereafter "CDC") pursuant to the Freedom of Information Act (hereafter "FOIA"). On January 4, 2023, CDC acknowledged the FOIA Request and denied Freedom Coalition's fee waiver request. Freedom Coalition writes now to appeal this denial.

Background:

On January 3, 2023, Freedom Coalition submitted a request to CDC for the following documents:

> *All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*

(Attachment 1.)

As part of its request, Freedom Coalition requested that CDC waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government. Freedom Coalition detailed three ways the disclosure of the requested information would contribute to that understanding. It stated:

> (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe

> participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization;(2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and
>
> (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the [Freedom Coalition] requests will not contribute to any commercial activities.

On January 4, 2023, CDC acknowledged the request, assigned it request number 23-00462-FOIA, and denied Freedom Coalition's request for a fee waiver stating in relevant part:

> You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:
>
> ☐ You have failed to demonstrate that you disseminate information to the public.
>
> ☐ You have failed to provide enough information to warrant a waiver of fees.

(Attachment 2.)

CDC issued a final response to the request on January 12, 2023, declaring "the agency is withholding the v-safe free-text-fields data." (Attachment 3.) Freedom Coalition submitted an appeal challenging the agency's withholding of responsive records, and the appeal was officially acknowledged on January 17, 2023. (Attachment 4.) Despite the passage of over 30 business days, CDC has failed to make any determination with respect to Freedom Coalition's appeal.

Argument:

CDC should waive any and all fees or charges associated with the processing of Freedom Coalition's FOIA Request because Freedom Coalition has sufficiently detailed how the requested information is in the public interest and likely to contribute significantly to the public understanding of the operations or activities of CDC. Additionally, even if it is determined Freedom Coalition is not entitled to a complete fee waiver, its status as an educational institution requester, or member of the media, entitles it to reduced fees and costs. Moreover, Freedom Coalition's entitled to reduced fees and costs because CDC failed to abide by the time limits of FOIA.

1. The requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government

Under FOIA, "[d]ocuments shall be furnished without any charge or [reduced] . . . if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. Furthermore, under FOIA, federal agencies are required to "promulgate regulations . . . specifying the schedule of fees applicable to the processing of requests . . . and establishing procedures and guidelines for determining when such fees should be waived or reduced." 5 U.S.C. § 552(a)(4)(A)(i). The U.S. Department of Health and Human Services ("HHS"), CDC's parent department, has promulgated regulations regarding fees and fee waivers applicable to FOIA Requests. 45 C.F.R. §§ 5.51 – 5.54.

HHS regulations provide that the agency "must furnish records responsive to a request without charge or at a reduced rate" if it determines that: (1) "[d]isclosure of the requested information would shed light on the operations or activities of the government"; (2) "[d]isclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities"; and (3) "[t]he disclosure must not be primarily in the commercial interest of the requester." 45 C.F.R. § 5.54(b). All three factors are present here.

a. Disclosure of the requested information would shed light on the operations or activities of the government

The disclosure of the information Freedom Coalition has requested – all data from v-safe's free-text fields – will shed light on the operations or activities of the government. As explained below, the relevant free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines. Therefore, the disclosure of the information will shed light on whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues that impacted its relevant policies or regulatory decisions and recommendations.

CDC claims that the current "COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in U.S. history[.]"[1] CDC also explained that its leading vaccine safety system, the Vaccine Adverse Events Reporting System ("VAERS"), was incapable of determining causation and was otherwise unreliable to assess the safety of COVID-19 vaccines. As a result, CDC deployed a new safety monitoring system for the COVID-19 vaccines: **v-safe**.

V-safe is CDC's premier safety system for tracking the safety of COVID-19 vaccines. V-safe is an online software program, accessible through the use of a smart phone, that allows vaccine recipients to "tell CDC about any side effects after getting the COVID-19 vaccine."[2] The purpose of the program, as explained by CDC, "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important

[1] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

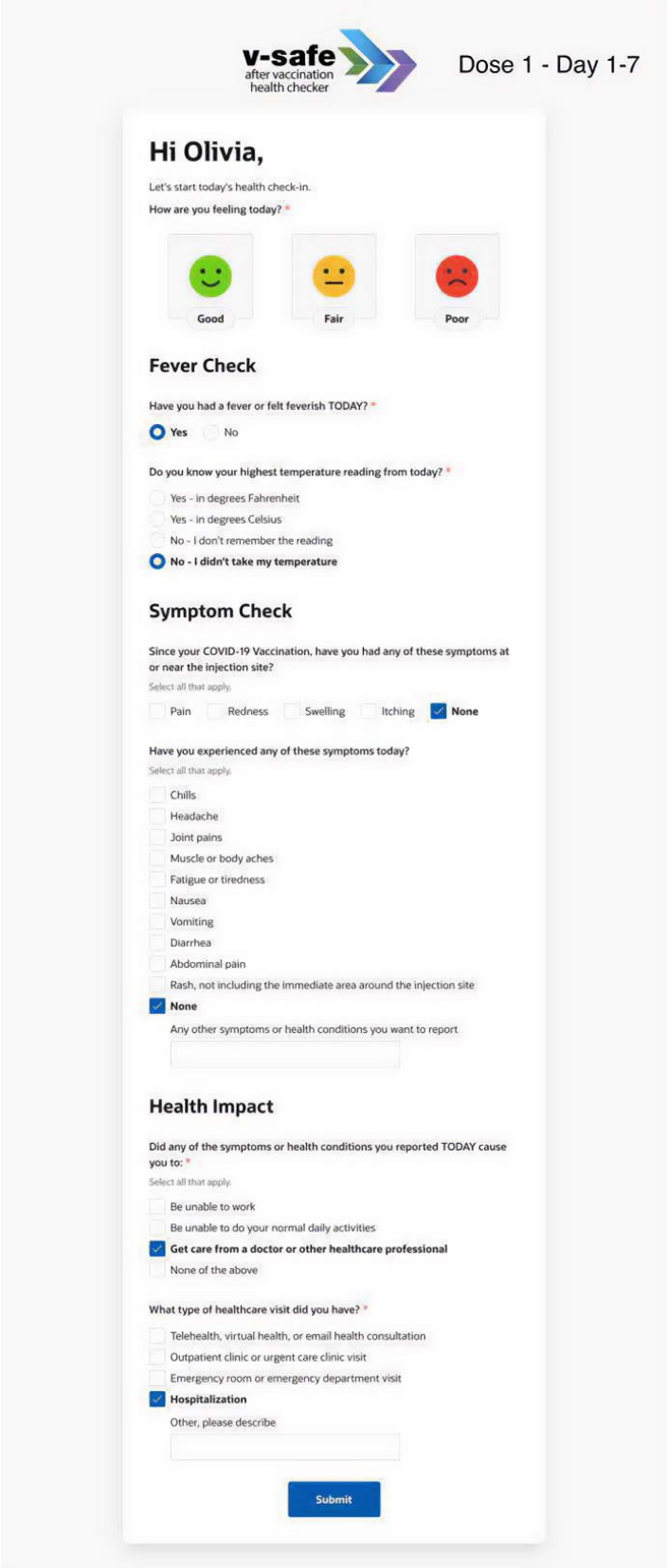
[2] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

adverse events and safety issues that might impact policy or regulatory decisions."[3]

V-safe collected COVID-19 vaccine safety information in two ways from its approximate 10 million users. The first is with check-the-box questions. The second is with free-text fields.

With regard to the check-the-box data collected, it is limited to two categories of information. The first asks v-safe users to select one or more of 10 symptoms that occurred within the first week after vaccination. For example, see the image below:

[3] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.


v-safe
after vaccination health checker
Dose 1 - Day 1-7
Hi Olivia,
Let's start today's health check-in.
How are you feeling today? *
Good
Fair
Poor
Fever Check
Have you had a fever or felt feverish TODAY? *
Yes
No
Do you know your highest temperature reading from today? *
Yes - in degrees Fahrenheit
Yes - in degrees Celsius
No - I don't remember the reading
No - I didn't take my temperature
Symptom Check
Since your COVID-19 Vaccination, have you had any of these symptoms at or near the injection site?
Select all that apply.
Pain
Redness
Swelling
Itching
None
Have you experienced any of these symptoms today?
Select all that apply.
Chills
Headache
Joint pains
Muscle or body aches
Fatigue or tiredness
Nausea
Vomiting
Diarrhea
Abdominal pain
Rash, not including the immediate area around the injection site
None
Any other symptoms or health conditions you want to report
Health Impact
Did any of the symptoms or health conditions you reported TODAY cause you to: *
Select all that apply.
Be unable to work
Be unable to do your normal daily activities
Get care from a doctor or other healthcare professional
None of the above
What type of healthcare visit did you have? *
Telehealth, virtual health, or email health consultation
Outpatient clinic or urgent care clinic visit
Emergency room or emergency department visit
Hospitalization
Other, please describe
Submit

This list of symptoms are the same symptoms CDC says are normal to occur after vaccination and are actually a sign the vaccine is working by producing an immune response.[4] Therefore, for the assessment of the overall safety of COVID-19 vaccines, it was pointless to gather this information regarding these 10 symptoms.

The only other check-the-box safety information collected (other than symptoms) is asking v-safe users whether they needed medical care, missed school or work, or could not perform normal daily activities (the "**health impact data**"). If the user selected needing medical care, they were then asked to select whether they sought telehealth, urgent care, emergency care, or were hospitalized. The health impact data, unlike the check-the-box symptoms data, is collected beyond the first week after injection, and is collected weekly for the first six weeks after injection, then again at 3, 6 and 12 months.

While the collection of the health impact data is an important part of gaging the safety of the COVID-19 vaccines, the free-text fields provide the only opportunity for v-safe users to report more complex and serious adverse events that occurred after vaccination. For example, in the first version of the v-safe protocol, prior to its launch, CDC identified the following adverse events of special interest in a chart titled Prespecified Medical Conditions:

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

(Attachment 5.)

CDC also identified many of these adverse events as potential harms of concern from COVID-19

[4] See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.

vaccines, in a presentation on October 30, 2020, titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[5] Despite CDC itself directly identifying these adverse events as harms of potential concern, it did not include check-the-box options for users to report these harms, nor did it even provide any check-the-box options for common symptoms from these harms. Instead, CDC oddly purposely chose to limit reporting of any such adverse events to the free-text fields, a data collection method that is far more difficult to standardize and tabulate.

CDC had an obligation to properly review and tabulate the data to detect and evaluate clinically important adverse events and safety issues.[6] Until this critical data obtained from these free-text fields is released to the public, there is no way for the public and scientific and medical community to determine whether CDC adequately acted upon *the most critical information it obtained from v-safe users.* In addition, the disclosure of this critical information will shed light on the legitimacy and reasonableness of the policy and regulatory decisions and recommendations CDC made with respect to the COVID-19 vaccines.

Therefore, the release of the requested information is in the public interest because it is likely to contribute significantly to the public's understanding of the operations or activities of the government. Thus, the first factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

b. Disclosure of the requested information would likely to contribute significantly to public understanding of governmental operations or activities

The disclosure of the data obtained from the free-text fields would significantly contribute to the public's understanding of whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues, and whether it implemented the correct policy or regulatory decisions based off the data it received. Currently, CDC claims it received 7.8 million free-text entries from v-safe users. (Attachment 3.) However, CDC has not allowed the public to assess the critically important data obtained from these free-text fields.

As explained in the section above, because of how CDC structured the v-safe program, these free-text entries provide the only opportunity to report serious adverse events in the v-safe system. Moreover, these free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines because they were collected from a known sample size of participants directly reporting their symptoms and reactions. Thus, the rate at which an adverse event is reported can be calculated and relied upon. Therefore, the disclosure of the requested information would likely contribute significantly to public understanding behind the legitimacy of CDC's numerous policy and regulatory decisions and recommendations based on its assertion that the COVID-19 vaccines are safe and serious adverse events are *statistically rare*.[7]

The numerous policy and regulatory decisions and recommendations CDC made regarding the COVID-19 vaccines played a major role in influencing large segments of society to mandate

[5] https://stacks.cdc.gov/view/cdc/97350 at 17.

[6] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[7] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

the receipt of the COVID-19 vaccines. Largely because of these vaccine mandates, more than 265 million Americans received at least one COVID-19 vaccine.[8] Therefore, a large segment of the public would likely be interested in learning the rates of serious adverse events that were reported in v-safe, CDC's premier safety system for tracking the safety of COVID-19 vaccine.

Freedom Coalition is in a unique position to facilitate the review, analysis, and dissemination of the information it receives from this request. Freedom Coalition is a nonprofit organization that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database. The coalition is made up of medical and public health professionals, scientists, and journalists. It takes no position on this data other than that it should be made available to the public and scientific community as soon as possible. All data obtained will be made available on its website, www.drsforchoice.org, upon receipt. Its network of uniquely qualified members and supporters will enable the information obtained from this request to be easily and meaningfully distributed to wide segment of the American public.

Therefore, the disclosure of the requested information would likely contribute significantly to public understanding of CDC's operations and activities. Thus, the second factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

c. The disclosure is not primarily in the commercial interest of the requester

The information Freedom Coalition seeks is not "primarily in the commercial interest of the requester." The disclosure of records from this request will not contribute to any commercial activities. Freedom Coalition is a non-profit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database. (Attachment 6.) It fully intends to disseminate the disclosed information for free and will not profit from the disclosure of the requested information. Thus, the third factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

Freedom Coalition has established all the criteria HHS and CDC find necessary to furnish records without charge, therefore the fee waiver request should be granted. 45 C.F.R. § 5.54(b).

2. Freedom Coalition is not an "Other Requester"

Even if CDC determines a full fee waiver is not appropriate, Freedom Coalition should be considered an educational institution requester, or a member of the media. As explained above, Freedom Coalition is a nonprofit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database.[9] It intends to provide access to the disclosed data to the public for free through its website, and its network of members and supporters which includes medical personnel and journalists. Therefore, at the very least, Freedom Coalition is "entitled to search time, review time, and up to 100 pages of duplication (or the cost equivalent for other media) without charge." 45 U.S.C. § 5.53(b).

[8] https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.

[9] https://drsforchoice.org/.

3. CDC is required to waive fees when it fails to abide by the time limits of FOIA.

CDC should waive or reduce fees because it failed to make a determination with respect to Freedom Coalition's appeal within the time limits prescribed by FOIA. An agency must make a determination with respect to a requester's appeal within 20 business days of its receipt. 5 U.S.C. § 522(a)(6)(A)(ii). If the agency provides an adequate notice of "unusual circumstances" the deadline for the agency's determination can be extended to a total of 30 business days. 5 U.S.C. § 522(a)(6)(B)(i). When an agency fails to comply with these deadlines "and agency shall not assess any search fees [or duplications fees]." 5 U.S.C. §522 (a)(4)(A)(viii)(I). Even when unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, an agency may not charge search or duplications fees unless the agency has discussed with the requester how it could effectively limit the scope of the request. 5 U.S.C. § 522(a)(4)(A)(viii)(II).

In this instance, CDC failed to make a determination with respect to Freedom Coalition's appeal within 30 days. Furthermore, CDC never discussed with Freedom Coalition how it could effectively limit the scope of the request. Therefore, Freedom Coalition should not have to pay all the fees CDC incurs or incurred during the processing of its request. 5 U.S.C. § 522(a)(4)(A)(viii)(I); 5 U.S.C. § 522(a)(4)(A)(viii)(II).

Appellate Request

For all the reasons detailed above, Freedom Coalition appeals CDC's fee waiver denial and requests the agency make a determination with respect to this fee waiver appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Regards,

/s Christopher Wiest

Christopher Wiest

Attachment 1

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

o modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
Attorney
Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd
Ste. 104
Crestview Hills, KY 41017
Phone 5132571895
chris@cwiestlaw.com

Requester Default Category: All Others

General Information

ction Office	HQ CDC/ATSDR FOIA Office
ction Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
equest Type	FOIA
equester Category	Non-Commercial Scientific
elivery Mode	E-mail

hipping Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

equest Information

escription	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
ate Range for Record earch:From	10/01/2020
ate Range for Record earch:To	12/31/2022
escription Document	CDC v-safe free text request.pdf

ee Information

illing Amount	$25
ee Waiver Requested	Yes ,CDC v-safe free text request.pdf
ee Waiver Request Reason	See attached.
illing to Pay All Fees	No

illing Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills

tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

ther Information

lame	
ompany	
hone	
ax	
mail Address	
treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

xpedite Information

xpedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

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[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 4, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated January 3, 2023. Your request assigned number is 23-00462-FOIA, and it has been placed in our complex processing queue (copy enclosed).

Extension of Time
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

☐ We reasonably expect to receive and review voluminous records in response to your request.
☐ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Irma S. Diaz at 770-488-6310 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing
You requested that we expedite processing your request. Your request is denied because:
☐ You have failed to show that there is an imminent threat to the life or physical safety of an individual.
☐ You have not demonstrated that you are a person primarily engaged in disseminating information.

Fees and Fee Waivers

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☐ You have failed to demonstrate that you disseminate information to the public.

☐ You have failed to provide enough information to warrant a waiver of fees.

Fee Category

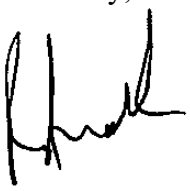
Because you are considered an "Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Appeal Rights

You have the right to appeal the agency's expedited processing and fee waiver response to your request. You may file your appeal with the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 5, 2023

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6310 or via email at jyo0@cdc.gov.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

23-00462-FOIA

Attachment 3

Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

January 13, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request* #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter "Organization"). On January 3, 2023, I submitted on behalf of the Organization a request for records (hereafter "FOIA Request") from the files of the Centers for Disease Control and Prevention (hereafter "CDC") pursuant to the Freedom of Information Act (hereafter "FOIA"). On January 12, 2023, CDC responded to the FOIA Request (hereafter "Final Response"). The Organization writes now to appeal the Final Response.

Background:

On January 3, 2023, the Organization submitted a request to CDC for the following documents:

> *All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*

(Attachment 1.)

On January 12, 2023, CDC issued a Final Response letter which stated in relevant part:

> *Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:*
>
> - *There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).*
>
> - *The agency lacks the resources to manually review the data collected from these registrants.*

> *Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.*

(Attachment 2.)

Argument:

CDC's withholding of the requested free text fields (hereafter "requested records") violates FOIA in two ways. First, CDC has failed to provide any exemption to justify withholding the requested records and a proper final 'determination.' Secondly, even if it has determined that portions of the requested records are not reasonably segregable, and they contain information relevant to protected privacy interests under Exemption 6, CDC has failed to demonstrate whether such privacy interests outweigh the public's interest in disclosure.

1. **CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records.**

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide the Organization with an adequate 'determination' as required under FOIA. When the sufficiency of "the release of information under the FOIA" is challenged, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). "[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C.§ 552(a)(6)(A)(i) ("notify the person making such request of such determination *and reasons therefor*."). "The statutory requirement that the agency provide 'the reasons' for its 'determination' strongly suggests that the reasons are particularized to the 'determination' — most obviously, the specific exemptions that may apply to certain withheld records." *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep't of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency "satisfied its obligation to 'determine and communicate . . . the reasons for withholding any documents" because they "provided reasons by listing and defining the exemptions that the agency applied to the records" withheld.) Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency's obligations under FOIA. *Khine*, 943 F.3d at 967-968.

In this instance, CDC's Final Response did not provide the information necessary to justify its reasoning for withholding records. CDC's Final Response declares "the agency is withholding the v-safe free-text-fields data" but never details the applicable FOIA Exemption that justify its withholding. (*See* Attachment 2). CDC claims all "7.8 million free-text field entries collected from registered users . . . contain personal identifiable information (PII)." *Id*. CDC further claims

that it "lacks the resources to manually review the data collected from these registrants." First, if CDC does not have the resources to manually review the free text fields, how does it know all 7.8 million free text entries contain PII. It does not adequately prove this assertion. Second, CDC has not provided any information on whether most – if not all – the PII can be removed through more automated mechanisms, as opposed to only "manual[] review." For example, Social Security numbers, birthdates, phone numbers, registrant numbers, city names, etc. can likely be redacted through automated mechanism, or at least this information could be flagged for relatively easy manual redactions. Furthermore, if the free text fields are represented in a standardized template, and the PII is routinely detailed in certain boxes or locations in the template, the agency can automate a redaction overlay, that redacts these PII locations on every record. Therefore, CDC has not provided sufficient reasoning to withhold the requested records. For all the reasons described above, CDC has failed to justify withholding the requested records and provide the Organization with a sufficient final 'determination.' *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d 188-89.

2. **CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public's interest under Exemption 6.**

Even if CDC could demonstrate that the unreasonably segregable portions of the requested records contain protected privacy interests, CDC has failed to demonstrate those interests outweigh the public's interests in the requested records. "An agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi AG Media LLC v. U.S. Dep't of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a de minimis, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must "weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy." *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep't of State v. Washington Post Co*., 456 U.S. 595, 598 (1982).

In this instance, CDC's Final Response makes no indication whether the release of the information it has proven cannot be reasonably segregated would cause a "clearly unwarranted invasion of privacy." *Lepelletier*, 164 F.3d 46. FOIA does not flatly prohibit the release of personal information that could cause an invasion of privacy. It only protects the release of personal information that would cause a clearly unwarranted invasion of privacy. Thus, the determination on whether an invasion of privacy is clearly warranted or not depends on the

public's interest and benefit in obtaining the released material. *Id*. In this case, the requested information the Organization seeks has insurmountable importance to the public, and yet CDC's Final Response provides no indication whether the public's interest in the requested records was even considered.

In consideration of this appeal, as CDC goes back to balance the privacy interests in non-disclosure versus the public's interest in disclosure, Organization provides the following information to emphasize the insurmountable public interest in the requested records:

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which CDC currently possesses but is refusing to disclose, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

Failure to disclose this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. This would compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.[4] That is, for example, the core mission of React-19, a non-profit comprised of many individuals, and medical professionals, seriously injured from COVID-19 vaccines.

The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harms – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated. The information derived from the free text fields can help provide information to alleviate some of these issues.

The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign in order to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] The refusal to disclose the requested records would deny families the information they need to provide their informed consent to the external pressures and

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id*.

messaging resulting from the current administration's actions.

Lastly, if the requested information is disclosed, the Organization will, and has the capacity to make the information immediately available to the public. The Organization is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

Appellate Request:

For all the reasons detailed above, the Freedom Coalition of Doctors for Choice appeals CDC's Final Response and requests the agency make a determination with respect to this appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.
Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

o modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
ttorney
hris Wiest, Attorney at Law, PLLC
5 Town Center Blvd
te. 104
restview Hills, KY 41017
hone 5132571895
hris@cwiestlaw.com

equester Default Category: All Others

eneral Information

ction Office	HQ CDC/ATSDR FOIA Office
ction Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
equest Type	FOIA
equester Category	Non-Commercial Scientific
elivery Mode	E-mail

hipping Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

equest Information

escription	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
ate Range for Record earch:From	10/01/2020
ate Range for Record earch:To	12/31/2022
escription Document	CDC v-safe free text request.pdf

ee Information

illing Amount	$25
ee Waiver Requested	Yes ,CDC v-safe free text request.pdf
ee Waiver Request Reason	See attached.
illing to Pay All Fees	No

illing Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills

tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

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mail Address	
treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

xpedite Information

xpedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

---

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 12, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd. Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 3, 2023. Your request assigned number is 23-00462-FOIA, seeking:

> *"All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).* Date range: 10/01/2020-12/31/2022."

Please click on the following link to download a copy of the public v-safe data released by CDC. The data contains the registrant codes for all participants: *https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d*

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).

- The agency lacks the resources to manually review the data collected from these registrants.

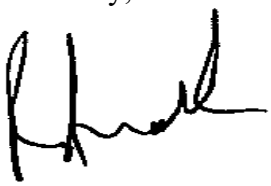
Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

Please click on the following link or copy into a web browser to download a copy of your records (download access is open for 90 days).
https://centersfordiseasecontrol.sharefile.com/d-s43a2254979c94ab6b5c52584509a351f

Appeal Rights

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 13, 2023.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#23-00462-FOIA

Attachment 4

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00067-A-PHS

January 17, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on January 17, 2023. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

Attachment 5

V-safe active surveillance for COVID-19 vaccine safety

Protocol summary

V-safe is an active surveillance program to monitor the safety of COVID-19 vaccines during the period when the vaccines are authorized for use under Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and possibly early after vaccine licensure. V-safe is a new smartphone-based system that uses text messaging to initiate web-based survey monitoring in the form of periodic health check-ins to assess for potential adverse events following vaccination. CDC will use the follow-up capability of the existing Vaccine Adverse Event Reporting System (VAERS) call center to conduct active telephone follow-up on recipients reporting a significant health impact during v-safe health check-ins. The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.

Background and significance

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Following the emergence of COVID-19 in China in late 2019, the first confirmed U.S. cases were detected in January 2020. With rapid human-to-human transmission occurring, the United States declared a public health emergency in February 2020, followed by a national emergency in March 2020 (1). As of November 18, 2020, there have been 11,300,635 cases of COVID-19 disease in the United States and 247,834 deaths (2). A key U.S. pandemic response initiative is Operation Warp Speed, a public-private partnership established in May 2020, with a goal to develop and deliver safe and effective COVID-19 vaccine(s) to the U.S. population by early 2021 (3).

Post-authorization/post-approval vaccine safety monitoring is a federal government responsibility, with the Centers for Disease Control and Prevention (CDC) and the FDA sharing most of the responsibility along with other federal agencies involved in healthcare delivery (e.g., Veterans Affairs, Department of Defense, Indian Health Service). Initial safety assessment

begins in early vaccine development and expands during phased clinical trials in humans. Clinical trials are effective at identifying and characterizing common adverse events, such as local and systemic reactions. However, even large clinical trials, like the COVID-19 vaccine clinical trials that are enrolling tens of thousands of volunteers, might not be large enough to detect rare adverse events (for example, those occurring at rates of <1 per 100,000 people vaccinated). Furthermore, for some clinical trials of COVID-19 vaccines, the follow-up period to monitor for possible adverse events with delayed onset may not be completed for all subjects prior to issuance of an EUA or licensure. Additionally, exclusion criteria for clinical trials may limit generalizability of safety and efficacy findings to special populations, such as those with certain chronic illnesses or pregnant women (4). For these reasons, robust post-authorization/approval safety monitoring of COVID-19 vaccines is a public health priority.

To meet the safety data needs for COVID-19 vaccine pharmacovigilance during the post-authorization/approval period, CDC will implement v-safe, a smartphone-based system that uses text messaging to initiate web-based surveys to monitor for adverse events following vaccination. The surveillance process triggers active telephone follow-up on vaccinated individuals reporting a significant health impact during v-safe health check-ins.

Goals and objectives

Goals

- Characterize the safety profile of COVID-19 vaccines.

- Rapidly monitor and identify potential safety problems associated with COVID-19 vaccines that would impact policy or regulatory decisions.

Objectives

- Characterize the local and systemic reactogenicity of COVID-19 vaccines during the first week post-vaccination (days 0-7).

- Identify and characterize clinically important adverse events following COVID-19 vaccination during a 6-week post-vaccination follow-up period.

- Monitor the long(er)-term (3, 6, and 12 months post-vaccination) safety of COVID-19 vaccines.

Methods

Surveillance population

All people in the United States who receive a COVID-19 vaccination will be eligible to enroll in v-safe for the duration of the v-safe program. Surveys will be available in English, Spanish, Simplified Chinese, Vietnamese, and Korean languages.

Enrollment criteria:

- Participants must have received a COVID-19 vaccination.
- Participants must possess a smartphone with a valid US telephone number. More than one individual may use the same smartphone/telephone number (i.e., shared smartphone).

Enrollment

The v-safe program will commence when COVID-19 vaccines are authorized or approved for use and become available to the U.S. population. Vaccination may occur at a mass vaccination clinic, an occupational health clinic, a public health clinic, a healthcare provider's office, a pharmacy, or other setting. At the time of vaccination, the healthcare provider will briefly describe the v-safe program using a prescribed script (Attachment 1). In addition, the healthcare provider will provide the vaccinated patient with an information sheet that includes a brief description of the program, a URL and a scannable QR code, and enrollment instructions.

Vaccinated individuals can enroll in v-safe immediately following vaccination. If they do not enroll immediately, they can decide to participate in v-safe at any time up to 42 days following the first vaccination. For vaccine recipients whose vaccination information is captured in CDC's Vaccine Administration Management System (VAMS), VAMS will send recipients a reminder text message about v-safe 24 hours after vaccination (5). Participation in v-safe is voluntary and

people can opt out at any time by texting “STOP” when v-safe sends a reminder text message; people can also start v-safe again by texting “UNSTOP.”

Once a vaccinated individual decides to enroll in v-safe, the individual will either scan his/her mobile phone camera over the QR code on the information sheet or type in the v-safe URL to access the v-safe registration website.

Registration information includes:

- First name
- Last name
- Mobile phone number
- Date of birth
- Sex
- Zip code

The registration system will ask the participant to verify their phone number by sending a text message with a verification code. The participant will enter the texted code to verify their identity. After that, the participant will be asked to record information on their first COVID-19 vaccination, including the vaccine manufacturer and the vaccination date. If the v-safe participant does not know this information, they are encouraged to refer to the vaccination record card they received or to contact their healthcare provider.

Once a participant has registered and provided information on their COVID-19 vaccination, they will be prompted to take an initial v-safe health check-in survey. The survey will be dependent on the vaccination date and dose number (if applicable) entered during registration. Subsequently, text messages will be sent to their smartphone with a link to a web-based survey at 2:00 pm (local time based on zip code entered at registration) on the schedule listed below.

Electronic health check-in schedule

The schedule for electronic health check-ins is as follows:

1. Day 0 (day of vaccination)

2. Daily on days 1-7 (the 1st week post-vaccination)

3. Weekly starting day 14 (2nd week post-vaccination) to up to day 42 (6th week post-vaccination) if no 2nd dose of COVID-19 vaccine is received

    a. If participant receive a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through steps 1-3 above based on time since the 2nd dose.

4. At 3, 6, and 12 months post-vaccination following 2nd dose vaccination or following first dose if no 2nd dose is received

Daily surveys expire at midnight on the day of the survey and weekly surveys expire at midnight on the last day of the week before the next weekly survey period. The day 42 survey will expire on day 48 at midnight. Monthly surveys will be available for 6 full days following receipt of the survey, expiring at midnight. A participant can enroll in v-safe up to 42 days during the post-vaccination follow-up period after the first dose, but cannot go back and complete surveys that have expired (i.e., it will be prospective from the time of enrollment). In addition, a participant cannot revise their survey once it has been submitted. After submission, the participant is told that depending on his/her answers, someone from CDC might call to follow up.

Active telephone follow-up

If, during any v-safe health check-in, a participant reports a significant health impact event, defined as per the survey: a) missed work, and/or b) unable to do normal daily activities, and/or c) got care from a doctor or other healthcare professional, VAERS call center staff will be informed and active telephone follow-up will be initiated to check on the patient and take a VAERS report if appropriate. VAERS is an existing national spontaneous reporting system that is co-managed by FDA and CDC. It serves as an early warning system for adverse events following vaccination (6).

VAERS call center staff will be notified of participants who have reported a significant health impact event via a data set that will be created from the v-safe survey system. The data set will include the following variables:

- Unique v-safe id
- First name
- Last name
- Phone number
- Sex
- Zip code
- Flagged health impact question
- Flagged health impact response(s) survey number (dose/survey [i.e., Dose2D0])

Using this information, the VAERS call center staff will call participants identified in the data set and complete a VAERS report (located at https://vaers.hhs.gov) by phone if appropriate.

Data collection, quality, and management

V-safe data will be collected, managed, and housed on a secure server by Oracle. Through Health and Human Services (HHS), Oracle has donated IT services to any agency conducting COVID-19 related activities. Oracle is providing IT support for v-safe. All data will be stored, processed, and transmitted in accordance with the Federal Information Security Modernization Act (FISMA) and based on NIST standards. Data will be housed in *Oracle Cloud Infrastructure (OCI) U.S. Government Cloud tenancy*; the OCI U.S. government tenancy is Federal Risk and Authorization Management Program (FEDRAMP) approved (7).

Per Oracle's internal policies, Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the CDC IT contractor's secure server. The v-safe system employs strict security measures appropriate for the level of sensitivity of the data. Data received by CDC will be stored on an internal secure CDC/ISO server and access will be limited to authorized personnel.

Oracle will create a data set for the VAERS call center that includes those participants who reported having a heath impact event. CDC-badged contractors will access these data in order to provide call center representatives with information needed to follow up with participants (see "Active telephone follow-up" above). The VAERS call center staff is employed specifically for v-safe follow-up and is associated with the overall VAERS contractor.

VAERS reports will be obtained during active telephone follow-up with v-safe participants and will be processed, handled, stored, and accessed in accordance with existing approved VAERS procedures and policies.

Data from all components of v-safe, as well as VAERS reports obtained through the call center, may be combined into a master data set behind the CDC firewall using unique identification numbers assigned at registration.

Preapproved CDC investigators and data managers, including CDC contractors, will be the only individuals with access to the full data (v-safe, linked VAERS reports). All electronic documents, data sets, and files relevant to the project will be stored on network folders with restricted access on CDC computers. The v-safe team at CDC will be primarily responsible for data management activities, including data extraction, documentation, and archival of a final data set for data sharing purposes. The archive will include the protocol, statistical programs, human subjects review documents, statistical output, analytical data sets, and manuscripts. It will clearly identify the permanent storage location for these files.

A final data set at the end of the v-safe program with deidentified aggregate data will be made available for external data requests or through Freedom of Information Act (FOIA) requests.

Analysis plan

Descriptive analyses will be conducted using the data collected through surveys on a weekly basis during the surveillance period. Participation rates over time will also be calculated.

For v-safe participants who have a VAERS report submitted through the VAERS call center, additional analyses will be conducted. Rates of serious events as well as adverse events of special interest (AESI) following COVID-19 vaccination will be generated using VAERS reports solicited via v-safe to define the numerator and v-safe participants as the denominator (Attachment 2). VAERS reports that are considered serious or AESI will be reviewed by medical staff at CDC. Case definitions (Brighton Collaboration or other standard definitions as appropriate) will be applied to the AESIs. Reporting rates for each AESI will be calculated and compared to established background rates. If at any time rates observed in v-safe exceed what is expected from background rates, further investigation will occur within other vaccine safety monitoring systems, including VAERS and Vaccine Safety Datalink (7).

VAERS monitoring for all COVID-19 reports will include VAERS reports solicited from v-safe participants. Reports obtained from v-safe participants will be coded so that they can be distinguished from other VAERS reports and analyzed separately from other VAERS reports if needed.

Human subjects considerations and confidentiality

This protocol will require human subjects determination at CDC since CDC is the lead site and surveillance data will include collection of PII. No PII will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests. Participation is completely voluntary and individuals self-enroll. Participants can opt out of v-safe at any time and their data will be used for the time they were considered an active participant. As an analysis of data collected for non-research purposes, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare.

Duration

The anticipated duration of the v-safe program is approximately 6-8 months of active enrollment. The decision to discontinue v-safe or to modify v-safe procedures to scale back active telephone follow-up will be made in consultation with the CDC COVID-19 Vaccine Task Force leadership and FDA.

Limitations and challenges

Limitations and challenges for v-safe surveillance include:

- Enrollment and registration will initially be a manual process and will be dependent on healthcare providers sharing information about the system with vaccine recipients. Enrollment might be limited. While VAMS will help promote v-safe enrollment though automated text message reminders, not all jurisdictions will use VAMS, and VAMS text messaging capabilities may not be rolled out until several weeks/months after vaccine becomes available.

- Accurate capture of vaccine manufacturer information will depend on accurate self-report, at least initially. Vaccine recipients are expected to receive vaccination record cards specifying the vaccine they received, which might help to improve accuracy of these data.

- Vaccinated people who choose to participate in v-safe might be different from those who decline; therefore, rates of side effects and adverse events generated from v-safe might not be generalizable to the full population of vaccine recipients.

- V-safe allows people to enter late in the post-vaccination monitoring period. The group of individuals who enroll in v-safe late might be heterogenous–those who simply neglected to enroll early, those who chose to enroll only after experiencing a clinically important adverse event, and others. Data collected from these individuals may need to be analyzed separately from data from those who enrolled early.

- The information provided by v-safe participants at 3, 6, and 12 months after vaccination might be impacted by recall bias.

- Participants will likely be lost to follow-up at later time points, reducing participant numbers and likely creating biases in v-safe analyses of safety out to 12 months.

- Because v-safe relies on vaccine recipients reporting their own experiences after vaccination, v-safe is not conducive to capturing the adverse event of death following vaccination.

Dissemination

Data from v-safe will be important in the beginning phases of the COVID-19 vaccination program. Regular updates will be provided to advisory committees and data review groups. It is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports.

References

1. *The American Journal of Managed Care*. A Timeline of COVID-19 Developments in 2020. Available at https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020.

2. CDC. CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days.

3. Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach. *N Engl J Med* 2020; 383:1701–1703.

4. Su JR, Duffy J, Shimabukuro TT (2019). Chapter 1: Vaccine Safety. In Poland GA (Ed.) and Whitaker JA (Assoc. Ed.), *Vaccinations*. St. Louis, MO: Elsevier.

5. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

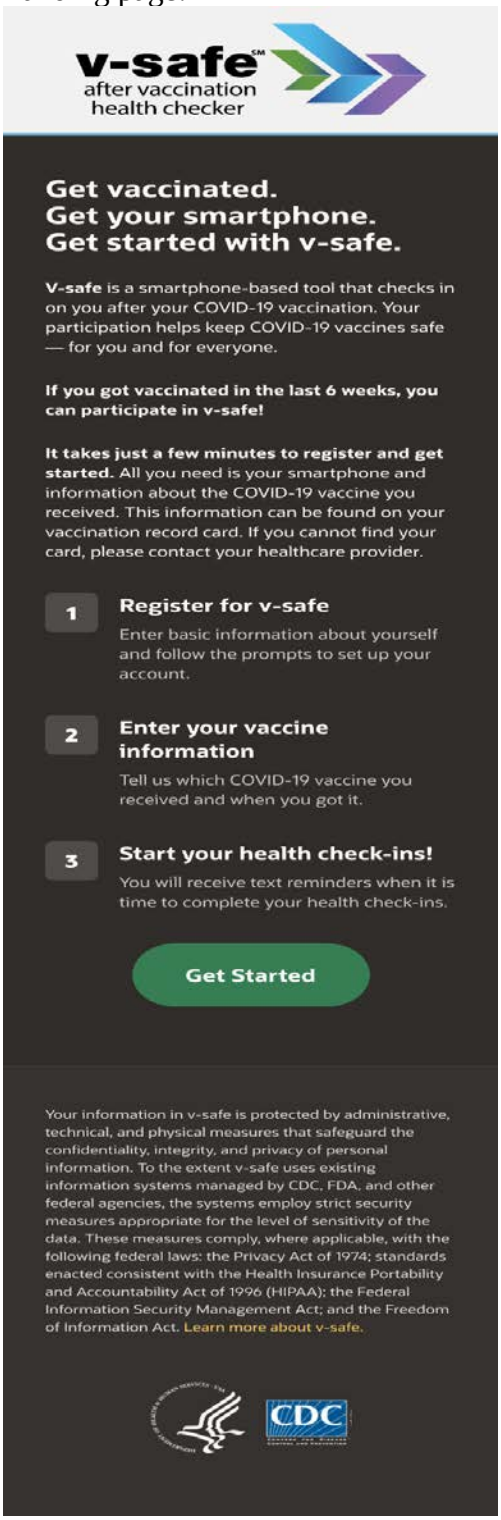
6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015; 33(36): 4398–4405.

7. *https://www.gsa.gov/technology/government-it-initiatives/fedramp)?*

8. McNeil MM, Gee J, Weintraub E, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine*. 2014; 32(42):5390–8.

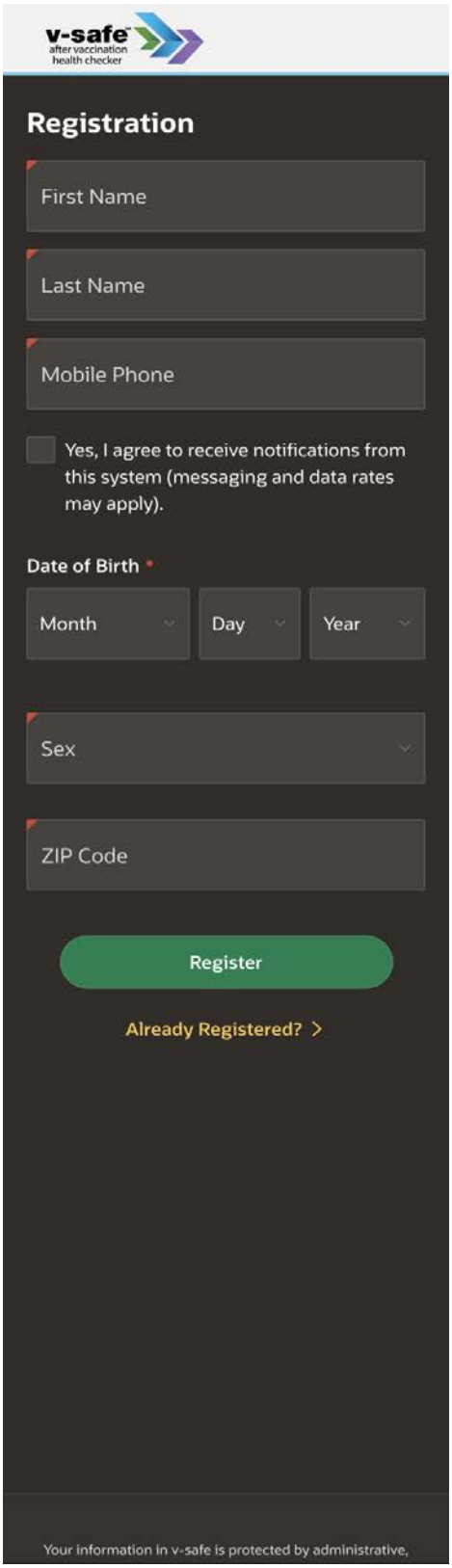
v-safe protocol: Nov 19, 2020

Attachment 1: V-safe survey script
Registration and my account:
Landing page:



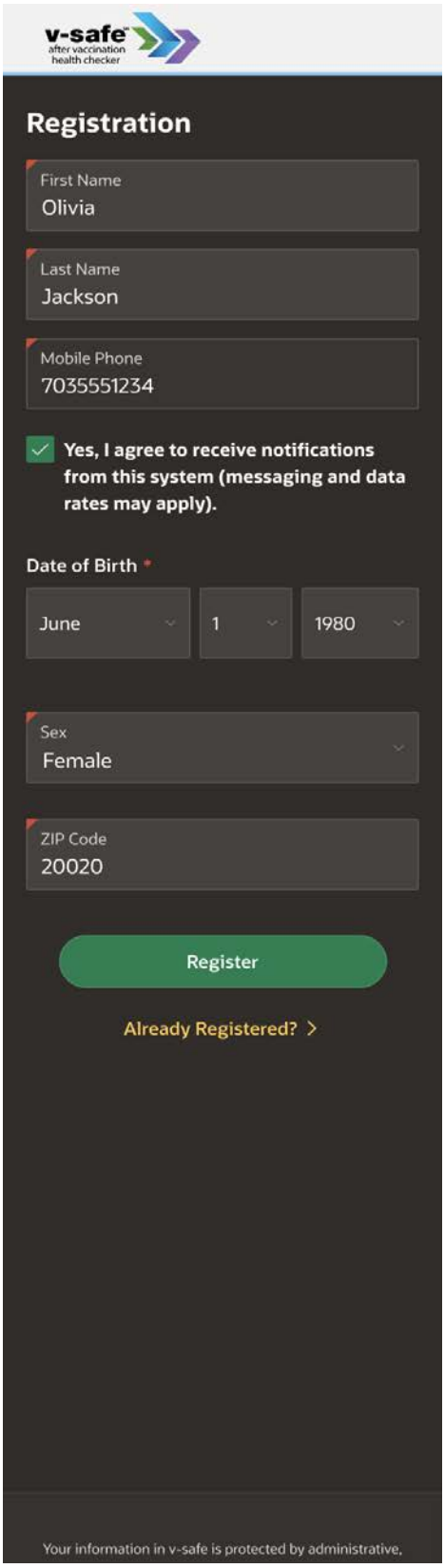
v-safe protocol: Nov 19, 2020

Registration page



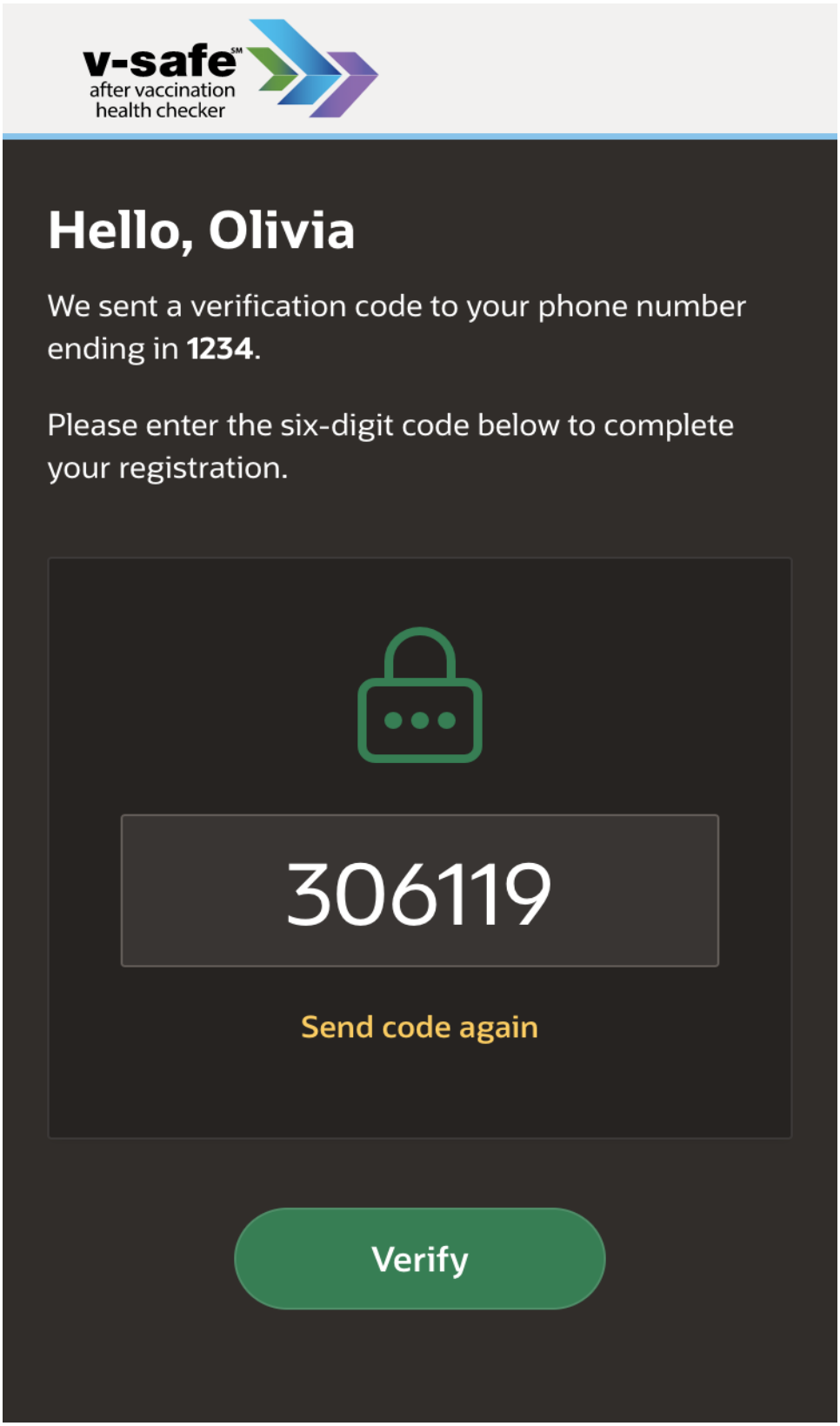
v-safe protocol: Nov 19, 2020

Registration completed:



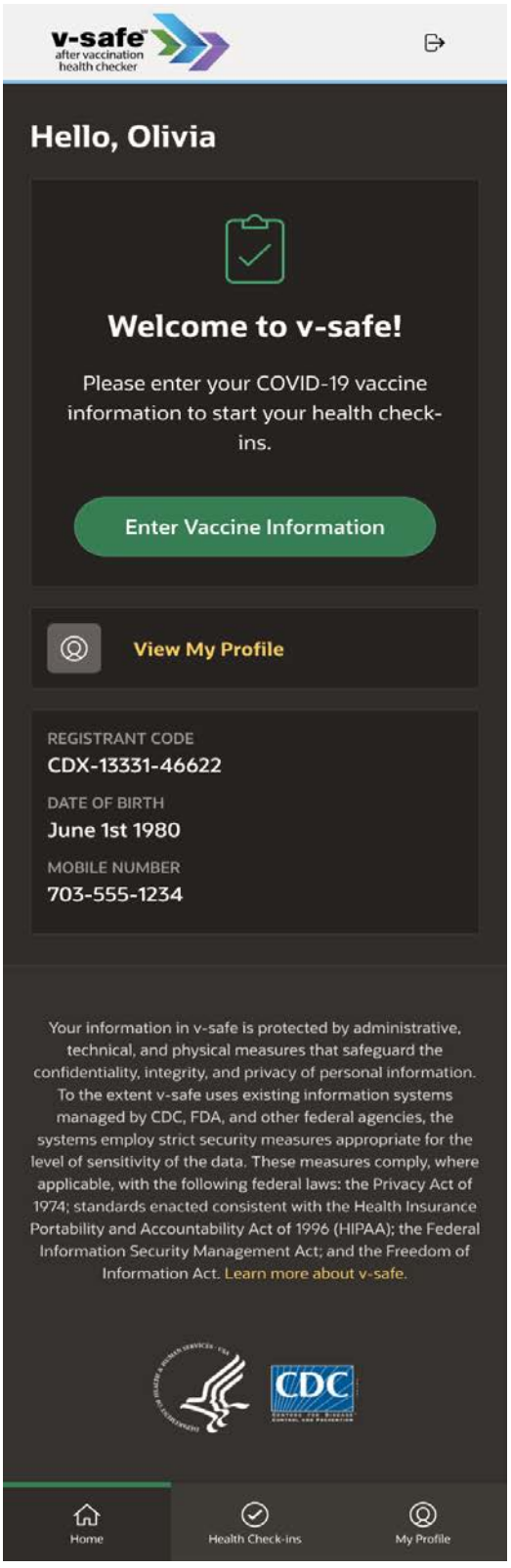
v-safe protocol: Nov 19, 2020

Verification:



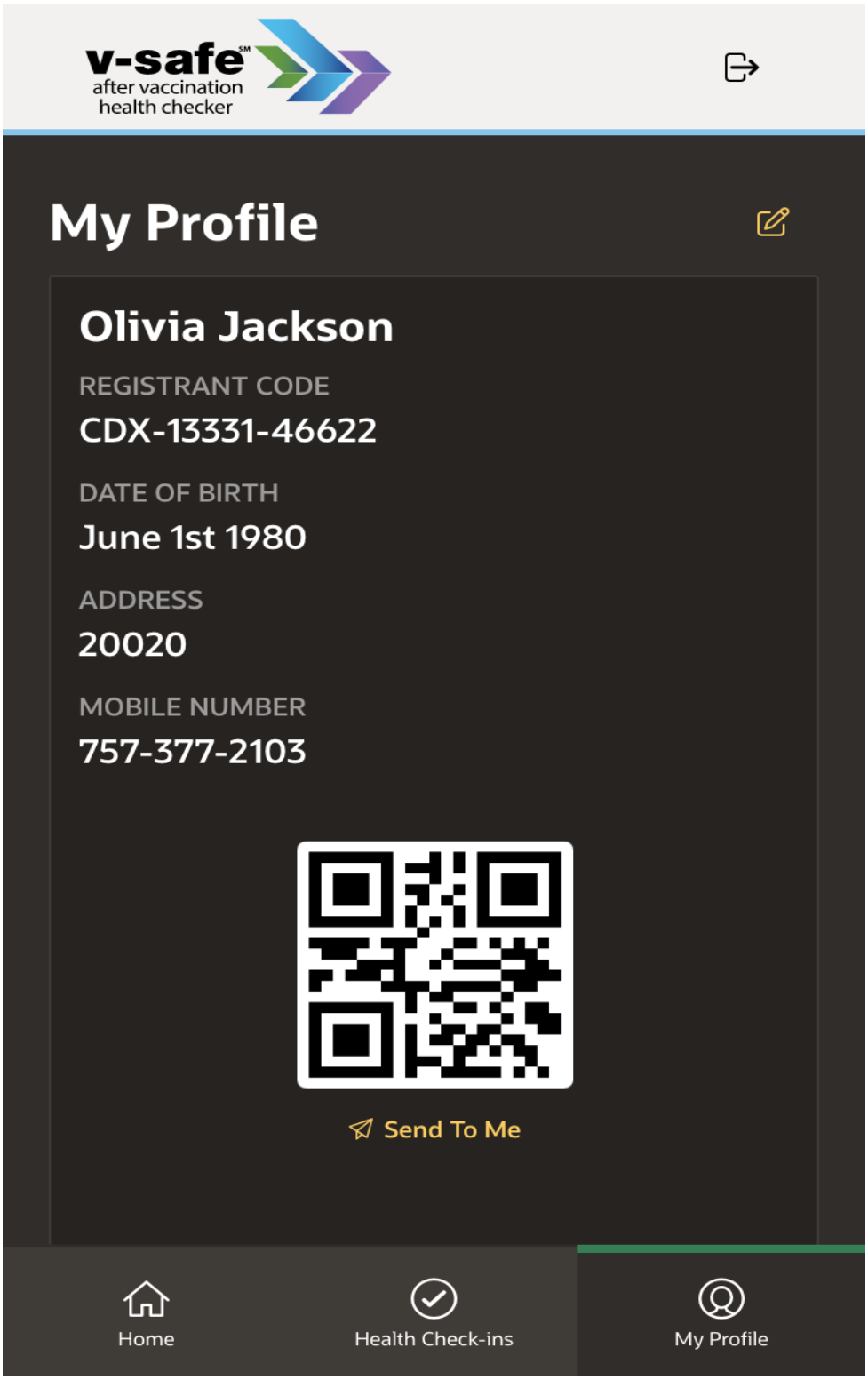
v-safe protocol: Nov 19, 2020

Account:



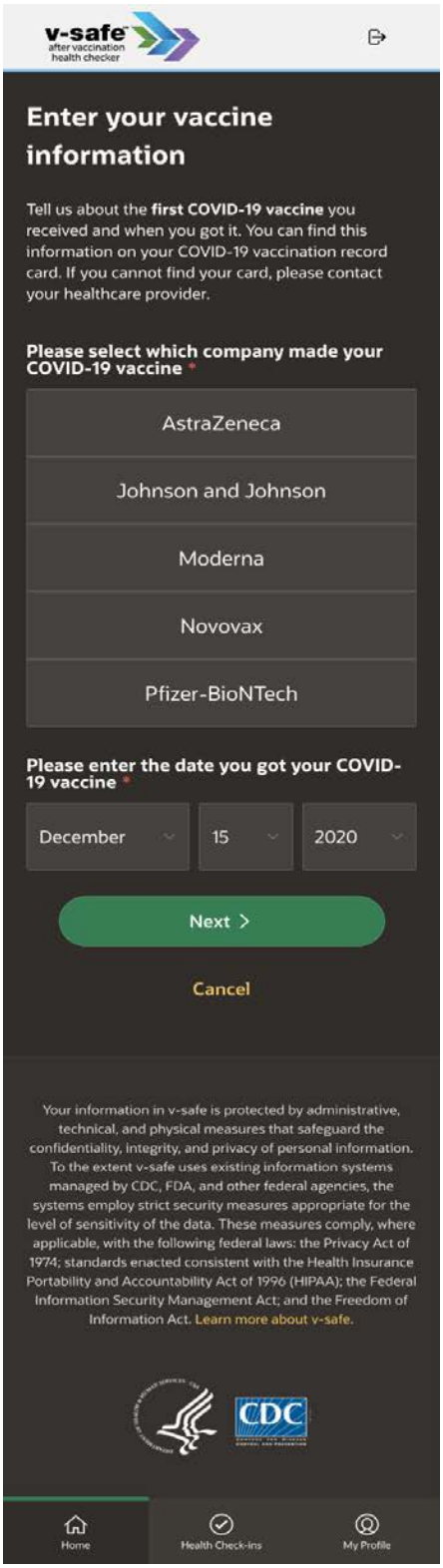
v-safe protocol: Nov 19, 2020

My profile:



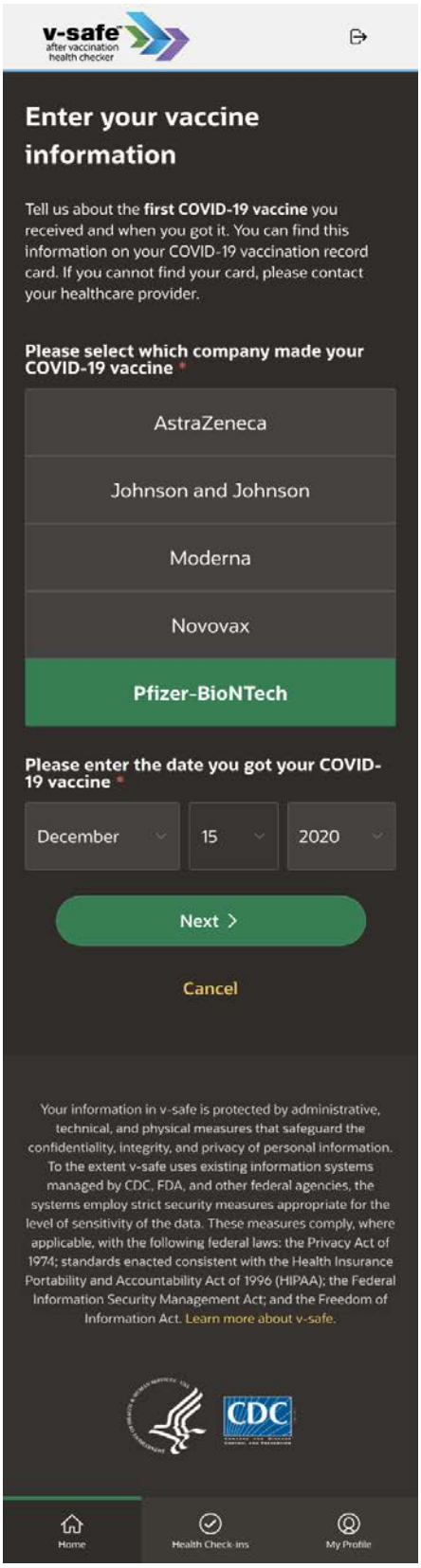
v-safe protocol: Nov 19, 2020

Enter vaccine:



v-safe protocol: Nov 19, 2020

Enter vaccine- completed:



v-safe protocol: Nov 19, 2020

Confirm vaccine:

v-safe protocol: Nov 19, 2020

V-safe Dose 1 surveys through Day 42

DAY 0- Dose 1:

Text message invitation::
Hi <NAME>. It's time for your first v-safe check-in. (*link to personalized v-safe survey)*

Survey:
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your vaccination, have you had a fever or felt feverish?
☐ Yes ☐ No

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit): _____
Enter your highest temperature reading from today (degrees Celsius): _____

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site?
select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐None

How would you rate your symptoms:

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

Have you experienced any of these symptoms today?
Select all that apply.
☐ Chills

v-safe protocol: Nov 19, 2020

☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site) ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the symptoms or health conditions you reported TODAY cause you to (select all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

v-safe protocol: Nov 19, 2020

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*

☐ ☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

v-safe protocol: Nov 19, 2020

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi, <name>. It's time for your daily v-safe check-in. (*link to personalized survey)*

Reminder text (for Day 7 survey only): Hi <name>, Please remember to do your daily v-safe check-in. ((*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site today?
Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

Have you experienced any of these symptoms today?
Select all that apply:
☐ Chills
☐ Headache

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☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Symptoms:
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limite your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site_ ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the symptoms or health conditions you reported today cause you to (Select all that apply):

☐ Be unable to work?
☐ Be unable to do your normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization

v-safe protocol: Nov 19, 2020

☐ Other, describe:

_____

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

14 days (2 weeks) survey following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe:

_____

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

v-safe protocol: Nov 19, 2020

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

Alternate onscreen completion message FOR PFIZER and NOVOVAX RECIPIENTS:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

21 days (3 weeks) following COVID-19 vaccination- DOSE 1:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For Pfizer/Novovax recipients:

Hi <name>.
Let's start today's health check-in.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.

(Survey will end and will be directed to enter Dose 2 information:)

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Moderna/AZ/Johnson & Johnson recipients & Pfizer/Novovax who did not get dose 2:

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check in, have you experienced any new or worsening symptoms or health conditions?
☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?
☐ Yes ☐ No

(If Yes) When were you diagnosed? _____ (mm/dd/yyyy)

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Moderna/AZ/:
Thanks for completing today's check-in.
Depending on your answers, someone from CDC may call you to check on you.
You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

28 days (4 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

For all Moderna, AZ and those Pfizer/Novovax who did not previously report Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2-dose vaccine recipients who report 'No' above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions:

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

v-safe protocol: Nov 19, 2020

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

v-safe protocol: Nov 19, 2020

35 days (5 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Let's start today's health check-in .

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?
☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

v-safe protocol: Nov 19, 2020

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

42 days (6 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey)*
Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

v-safe protocol: Nov 19, 2020

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization
☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

How would you describe your current state of health?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

How is your health now compared to your heath before your last COVID-19 vaccination?

☐ Better
☐ About the same
☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

☐ Yes
☐ No

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if this is the first survey then question below is not asked)*
☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?
(*This is only asked if participant answered above pregnancy question in a previous survey)*

v-safe protocol: Nov 19, 2020

- ☐ Yes
- ☐ No

Onscreen completion thank you message:
For all vaccine recipients at Day 42:
Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch

v-safe protocol: Nov 19, 2020

V-safe Dose 2 surveys through Day 42:

Dose 2

Day 0 post vaccination

Text Message after + 2nd vaccine info completed

Hi <NAME>. It's time to check-in with v-safe for your 2nd vaccine dose. (*link to personalized v-safe survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your second COVID-19 vaccination, have you had a fever or felt feverish?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Since your second COVID-19 vaccination, have you had any of these symptoms at or near the injection site?

Select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching

(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe

v-safe protocol: Nov 19, 2020

(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you experienced any of these symptoms today?
Select all that apply.
☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Medical symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms cause some limitation of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible"

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site) ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the symptoms or health conditions you reported TODAY cause you to (Select all that apply):

☐ Be unable to work?
☐ Be unable to do your normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

v-safe protocol: Nov 19, 2020

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your answers, someone from CDC may call to check on you.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

v-safe protocol: Nov 19, 2020

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi <name>. It's time for your daily v-safe check-in. (*link to personalized survey)*

Reminder text (only sent for Day 7 survey, 3 days after original text sent): Hi <name>. Please remember to do your daily v-safe check-in. ((*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site today?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

Have you experienced any of these symptoms today?

v-safe protocol: Nov 19, 2020

Select all that apply:

☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Medical symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms cause some limitation of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible"

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site_ ☐ Mild ☐ Moderate ☐ Severe

Health impact

Did any of the symptoms or health conditions you reported today cause you to (Select all that apply):

☐ Be unable to work?
☐ Be unable to do your normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit

v-safe protocol: Nov 19, 2020

☐ Hospitalization

☐ Other, describe:

_____

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

v-safe protocol: Nov 19, 2020

Weekly surveys: Days 14, 21, 28, 35– Dose 2

Text message and reminder:
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions:

(if Yes) "Did any of these symptoms or health conditions cause you to (check all that apply):"

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) "What type of healthcare visit did you have? (check all that apply)"

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

v-safe protocol: Nov 19, 2020

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

□ Yes □No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

v-safe protocol: Nov 19, 2020

42 days (6 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey)*
Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) "Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

How would you describe your current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
- ☐ No

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 2; if this is the first survey then question below is not asked)*
☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?
(*This is only asked if participant answered above pregnancy question in a previous survey)*

- ☐ Yes
- ☐ No

Onscreen completion thank you message:

Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch in a few months.

v-safe protocol: Nov 19, 2020

V-safe 3, 6 and 12 month surveys:

Monthly survey
Hi <name>.
Since we last contacted you, have you experienced any new symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Since your last check-in, have you had a home or laboratory pregnancy test that was positive?

☐ Yes
☐ No

v-safe protocol: Nov 19, 2020

How would you describe your current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
- ☐ No

Onscreen completion thank you message:

3/6 Month:
Thanks for completing today's check in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, someone from CDC may call to check on you.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe.

12 Month:
Congratulations! You have completed your final v-safe check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Thank you for participating in v-safe! Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Take care and stay safe.

v-safe protocol: Nov 19, 2020

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

Attachment 6

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

CERTIFICATE OF FILING
OF

Freedom Coalition of Doctors for Choice
File Number: 804899545

The undersigned, as Secretary of State of Texas, hereby certifies that a Certificate of Formation for the above named Domestic Nonprofit Corporation has been received in this office and has been found to conform to the applicable provisions of law.

ACCORDINGLY, the undersigned, as Secretary of State, and by virtue of the authority vested in the secretary by law, hereby issues this certificate evidencing filing effective on the date shown below.

The issuance of this certificate does not authorize the use of a name in this state in violation of the rights of another under the federal Trademark Act of 1946, the Texas trademark law, the Assumed Business or Professional Name Act, or the common law.

Dated: 01/26/2023

Effective: 01/26/2023

Jane Nelson
Secretary of State

Exhibit H

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00117-A-PHS

April 3, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on April 1, 2023. It challenges the Centers for Disease Control and Prevention (CDC) denial of your request for a fee waiver for initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

Exhibit 2

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, Plaintiff, -against- CENTERS FOR DISEASE CONTROL AND PREVENTION, AND DEPARTMENT OF HEALTH & HUMAN SERVICES, Defendants.	Civil Action No. 2:23-cv-00102

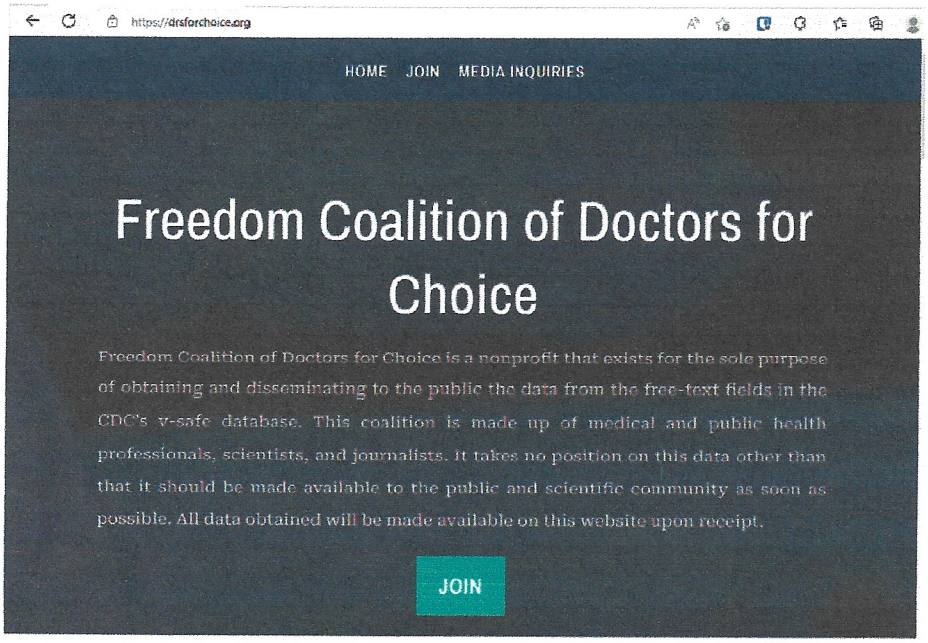
DECLARATION OF DR. RICHARD BARTLETT

I, Dr. Richard Bartlett, declare as follows:

1. I am an emergency room physician practicing in Amarillo and Lubbock, Texas.
2. The purpose of this declaration is to support Plaintiff's motion for summary judgment.
3. I make this Declaration based upon my personal knowledge and information available to me in my professional and personal capacity.
4. I identified and advocated for the use of budesonide in the treatment of COVID-19, which has become a treatment option in hospitals across the country, including Odessa Medical Center and Odessa Regional Medical Center. The therapeutic effect of budesonide was confirmed by Oxford University in multiple randomized controlled trials, including the STOIC TRIAL in which Oxford concluded that 90% of COVID hospitalizations could have been prevented with budesonide.
5. Plaintiff Freedom Coalition of Doctors for Choice (**"Freedom Coalition"** or **"Plaintiff"**) is a not-for-profit that we formed in order to obtain and disseminate to the public the

v-safe free-text data. I am one of the board members of Freedom Coalition and the coalition is made up of medical and public health professionals, scientists, and journalists. We take no position on this data other than that it should be made available to the public and scientific community as soon as possible. All data obtained will be made available on our website, www.drsforchoice.org, once it is produced.

6. As provided on our website, our mission is as follows:



7. Freedom Coalition currently has 91 members, including at least 46 medical doctors, 16 PhDs, 21 nurse practitioners or registered nurses, as well as professors from medical schools, including from UCLA and the University of Texas.

8. Freedom Coalition's headquarters is and has been at 600 S Tyler St, Suite 2100 #177, Amarillo, TX 79101 and our most recent board meeting was held on March 29, 2023 at its headquarters in Amarillo, TX, which is the usual and customary location of its board meetings. The Freedom Coalition has six board members. Three of them reside in

Amarillo (Drs. Pia and Rolf Habersang, and Dr. Deborah Moore), and I work in Amarillo.

9. Dr. Deborah L. Moore lives in Amarillo and her medical office is located at 6141 West Amarillo Boulevard, Amarillo, Texas 79106. Dr. Moore is a family medicine doctor and is the physician-owner and founder of a well-respected family medicine practice in Amarillo. Dr. Moore received her medical degree from Texas A&M Health Science Center College of Medicine and recently published a book titled *Covid Treatment: A Clinician's Guide and Commentary on the Management of Covid-19* based on her clinical experience treating patients with COVID-19.

10. Pia Habersang, EdD, CNS, MSN, APRN is a primary care provider with over 40 years of experience with children in hospital and outpatient settings. In 2013, Dr. Habersang founded the Pediatric Wellness Center of Amarillo located at 1901 Medi Park Drive, Suite # 110, Amarillo, TX, where she currently practices. Her Doctorate in Child and Youth Studies prepared her to apply knowledge of early childhood developmental milestones throughout adolescence into primary care.

11. Rolf Habersang, MD, MPH, and TM is a physician in Amarillo. He previously specialized in pediatric critical care medicine in Amarillo and was affiliated with multiple hospitals in the area. He received his medical degree from University of Basel Switzerland. He has been practicing and teaching since 1973 as a Professor in the Department of Pediatrics at Texas Tech University Health Sciences Center. In 2002, Dr. Habersang founded Integrated Complementary Alternative Medicine in Amarillo, where he takes care of mostly adult patients, while still seeing some patients at Texas Tech on a part-time basis. Dr. Habersang is also the supervising and supportive physician at the

Pediatric Wellness Center of Amarillo (founded in 2013), located at 1901 Medi Park Dr. Suite # 110, Amarillo, TX where he co-manages patient care with Dr. Pia Habersang.

12. Camilla Glenn, APRN, FNP-C is a primary care provider practicing in Lubbock, Texas who worked for a medical organization that laid her off because they disfavored her providing informed consent to patients regarding COVID-19 vaccines.

13. Dr. Paul Thomas is a general surgeon practicing in Lubbock, Texas and the founder of Operation H.O.P.E. USA, a non-profit that, among other things, provides medical care in areas of the world where there may be scant or no capable medical service.

14. Delays in disclosing the requested v-safe data prevent the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. These delays compromise the public's significant recognized interest in transparency and informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treat those who have already been harmed. That is, for example, the core mission of numerous groups that have formed to treat individuals injured by COVID-19 vaccines.

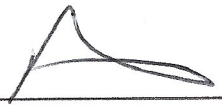
15. For example, React19 is a group comprised of over 30,000 individuals, including hundreds of medical professionals, who have been seriously injured by a COVID-19 vaccine. They are desperately seeking reliable data that can help explain the harms suffered among their members, which are currently only being observed in a non-systematic fashion. Until these harms are scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments.

16. Moreover, irrespective of how many people complain of the harm – even if there are tens of thousands – without systematic datasets, the medical health establishment considers these complaints as mere anecdotes. Thus, these harms are allowed to continue dangerously unabated; this will not change until the public, including groups like React19, and doctors such as myself can get the data needed to systematically show what harms are caused by COVID-19 vaccines; they desperately need v-safe's free-text data to have a systematic dataset that may scientifically validate their harms so that the medical community will acknowledge them and then provide medical care.
17. Freedom Coalition is seriously concerned about the fact that CDC was not transparent about the v-safe information with the public—that it hid the real rates of health impact from COVID-19 vaccines from the public for over two years while misleadingly revealing only the first week of data. Freedom Coalition finds this lack of transparency deeply troubling and wants the full v-safe dataset made public immediately so that independent scientists can review this data—paid for by the American people—to assess what injuries COVID-19 vaccines may cause in order to prevent further injuries and advance treatment for those injured.
18. CDC has published two studies the Freedom Coalition can identify that involve free-text data.
19. Freedom Coalition and independent scientists need the requested free-text data—data that actually provides critical information to assess the safety of the COVID-19 vaccines— in order to conduct meaningful studies.

20. Therefore, Freedom Coalition sought from CDC: "All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry."
21. CDC refused to disclose the data claiming "the agency lacks the resources to manually review the data collected."

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury the foregoing to be true and correct, to the best of my knowledge, information and belief.

Executed this 4th day of July, 2023.



DR. RICHARD BARTLETT